

THE HEARING AID MARKETPLACE: IS THE
CONSUMER ADEQUATELY PROTECTED?

Y 4. AG 4:S. HRG. 103-361

The Hearing Aid Marketplace: Is the...

HEARING
BEFORE THE
SPECIAL COMMITTEE ON AGING
UNITED STATES SENATE
ONE HUNDRED THIRD CONGRESS
FIRST SESSION

WASHINGTON, DC

SEPTEMBER 15, 1993

Serial No. 103-12



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THE HEARING AID MARKETPLACE: IS THE CONSUMER ADEQUATELY PROTECTED?

WEDNESDAY, SEPTEMBER 15, 1993

**U.S. SENATE,
SPECIAL COMMITTEE ON AGING,
*Washington, DC.***

The committee met, pursuant to notice, at 10:05 a.m. in room DG-50, Dirksen Senate Office Building, Hon. David Pryor (chairman of the committee) presiding.

Present: Senators Pryor, Grassley, Cohen, Kohl, Jeffords, Feingold, and Pressler.

Staff present: Theresa Forster, staff director; Gregory Smith, chief counsel; Mary Berry Gerwin, minority staff director; Helen Albert, investigator; and Priscilla Hanley, professional staff.

OPENING STATEMENT OF SENATOR DAVID PRYOR, CHAIRMAN

The CHAIRMAN. Good morning, ladies and gentlemen. We want to thank all of you for attending our hearing of the Special Committee on Aging, relative this morning to hearing aids.

First, we want to say a special word of thanks to our guests who will be on our panels this morning. Some have come from a long distance; we're very, very appreciative of your attendance.

Also, let us take note of the fact that this afternoon begins the Jewish period, and the Senate will be out of session early in the afternoon.

We're going to have several votes this morning, it appears, so Senator Cohen, myself, Senator Kohl, and others will be running back and forth from the committee, and we'll try to make this hearing just as smooth as possible, notwithstanding those interruptions, so we hope that you will understand that.

Also, upstairs in the Finance Committee, of which I'm a member, we're holding our first hearing on NAFTA, and I will probably have to go upstairs a time or two for that particular meeting. So this is just one of those days where we're supposed to be several places at once.

I want to give you a quote this morning to start our hearing off and see if any of you might remember who said it before I tell you:

More than 20 million Americans are believed to have some form of hearing impairment, from total deafness to mild loss. Many can be helped immeasurably by a hearing aid, many cannot be helped at all.

At the present time, according to estimates, most persons with a hearing impairment first go to a hearing aid dealer for assistance. This places tremendous responsibility on the dealer. He must be able to detect whether the hearing impaired person is a candidate for a hearing aid, on which the dealer makes a profit, or whether he should be referred to a physician, which may mean no business for the dealer.

The first question that we shall ask the hearing aid dealer is if he is truly qualified. A regulation now being developed at the Food and Drug Administration addresses this critical issue.

With National health insurance on the horizon, if the FDA by regulation institutionalizes the present hearing aid delivery system, it will likely be folded into any health insurance program adopted by the Congress.

Those words are not mine. They were spoken nearly 20 years ago by Senator Percy of Illinois when he chaired a Senate subcommittee hearing on the hearing aid industry. Yet, his words are still relevant as we look at today's hearing aid marketplace. Our ultimate goal now, as it was then, is affordable, appropriate, accessible hearing health care for all hearing impaired individuals.

Making the decision to purchase a hearing aid is not an easy one. First, the individual must make the difficult admission that he or she has a permanent physical impairment. Next, the individual must come to terms with the notion of wearing an assistive device. In the past, hearing aids were much larger and more cumbersome, and there was a stigma attached to wearing them. Fortunately, the example of many well-known public figures (among them former President Ronald Reagan, Former Surgeon General C. Everett Koop, Arnold Palmer, and my good friend and mentor Senator Claude Pepper, to name a few) and technological improvements which have allowed for the down-sizing of hearing devices have helped to ease concerns in this area.

I would like to mention that while preparing for this hearing I was reminded of a story I heard in recent years of a time when Senator Pepper, at the young age of 88, was being fitted for a new hearing aid. When given the choice between the purchase of 5 years' worth of batteries for the device and a lifetime supply, he, of course, chose the lifetime supply. I don't know whether that says more about his confidence in the hearing device he was purchasing or in his wonderful, positive outlook on life and living. He is an example to us all.

With respect to securing hearing care, an individual seeking a hearing aid must next have access to the care necessary to assess hearing loss and the cause of loss, and to determine what steps can be taken to assist the individual. Access, in this regard, is not always an easy matter, particularly in rural and underserved areas. Additionally, it is important for an individual seeking care to have confidence in the provider. Finally, the cost of the hearing device prescribed for use must also be affordable. I'd like to take a few moments to address each of these three areas of concern.

Confidence in the hearing care provider is critical. Hearing aids can and do provide meaningful assistance to the hearing impaired. Yet, there are some individuals that cannot be helped with hearing aids. All nonmedical providers must be trained to recognize when hearing aids are appropriate and when they are not. States must do more to set minimum competency standards for licensing, and they must enforce those standards. Unfortunately, we all hear horror stories about the unscrupulous sales practices of a few which hurts consumer confidence. On a Federal level we must continue to monitor advertising that induces consumers to purchase hearing aids through in-home and mail order sales.

Today's hearing is not to condemn one group of hearing health care providers in favor of another. Instead, we want to learn where

each member of the hearing health care team fits. The hearing specialist, audiologist, and otolaryngologist all have a role to play in providing hearing health care.

Despite some of the more troubling marketplace issues we will address today, I am truly amazed at the advances in hearing aids. Hearing aid technology has greatly benefited from developments in telecommunications and electronics over the past decade. In response to public demand for cosmetic acceptability, microchip technology has led to miniaturization of hearing aids such that 80 percent of the current market is for all-in-the-ear or canal aids. Programmable devices allow for tailoring to individual hearing loss and needs. Some aids allow multiple frequency responses to be programmed and stored for use in different listening situations. And, digital signal processing technology (DSP) can sense and cancel acoustic feedback on high power aids.

But all of these advances are not without their costs. And hearing assistance devices are, for the most part, an out-of-pocket expense. The fact underscores the importance of adequate consumer protections in the hearing aid marketplace to ensure against a drain on retired individuals' limited incomes.

Those of us who are fortunate enough to have normal hearing may take it for granted. We don't realize how much hearing impacts our daily lives. Imagine a world without sound or of only hearing partial sounds. That is what the hard-of-hearing person experiences.

As difficult as impaired hearing may be for any person, it is compounded for elderly persons. Of the approximately 23.5 million Americans that suffer hearing loss, more than 50 percent of them are over the age of 65. The loss of hearing affects their independence and quality of life. For many older people, hearing impairment prevents complete participation in everyday life. Simply trying to understand what is being said around them can be a frustrating experience. Beyond the inconvenience created by hearing loss, hearing impairment can lead to paranoia and depression. For many, purchase of a hearing aid can provide a lifeline to more enjoyable, useful, independent lives, and increased purpose for living.

Today we will hear from a broad cross-section of groups and individuals interested in the delivery of hearing care in the United States. I'm sure we all share the same commitment to ensuring the public—and especially senior citizens who purchase more than half of all hearing aids purchased in this country—can purchase these important device with confidence. I want to thank all our witnesses for coming to talk to us today and I look forward to hearing from each of you.

[The prepared statements of Senators Shelby, Riegle, Simpson, Durenberger, and Craig follow:]

PREPARED STATEMENT OF SENATOR RICHARD SHELBY

Mr. Chairman, I commend you for scheduling this hearing today to discuss our concerns regarding the marketing of hearing devices with particular emphasis on advertising and sales practices. I am very pleased that the AARP has completed a report on this issue which it plans to release at this Hearing and I look forward to hearing and examining this information.

We are fortunate to have a distinguished panel of witnesses with us this morning who will provide this Committee with some valuable insight into this problem. I regret that some of you have been victims of questionable sales practices; however,

I am very hopeful that this Hearing will identify ways to help us to adequately protect you and other consumers from unscrupulous sales tactics.

Presently, almost 23.5 million Americans suffer from hearing loss, and 60 percent of these individuals are Seniors. Because of the excessive costs of the devices, only a little more than 3½ million or 17 percent of the hearing impaired population wear hearing aids. In addition, neither Medicare nor most insurance policies cover the costs of hearing devices.

Although the price of hearing devices is of real concern to me, I find the lack of safety regulations regarding the dispensing of hearing aids to be much more problematic. Because of the lack of regulation in the industry, there is considerable abuse in the selling of hearing devices—people with little hearing loss are sold hearing aids, and people who cannot be helped by hearing aids are sold hearing devices.

Both the Food and Drug Administration (FDA) and the Federal Trade Commission are responsible for regulating hearing aids. It appears, however, that even though the FDA requires that consumers be advised by the hearing aid dispenser to take a doctor's examination before purchasing a hearing device or sign a written waiver of the medical exam, there may be misrepresentations of the waivers to the buyers. The FDA has found the number of waivers to be too high. I am very pleased that Commissioner Kessler of the FDA has agreed to testify before this Committee today because I know that he will be able to enlighten us regarding this matter and many other issues of concern.

Hearing aids can be dispensed by physicians, audiologists, or hearing aid dealers and the laws vary for each group; consequently, there is sometimes considerable confusion in the application of the regulations. Since the states are primarily responsible for regulating the hearing aid industry, I am hopeful that this Hearing will thoroughly examine the manner in which State Licensing boards operate.

It is my hope that the President's health care reform proposal will incorporate some of this Hearing's recommendations for the marketing of hearing aids. I want to thank the witnesses for being with us today and I am eager to hear your views on this issue.

PREPARED STATEMENT OF SENATOR DON RIEGLE

Mr. Chairman, because this is my first hearing as a member of the Aging Committee, I would just like to say that I am delighted to be a member of this committee and look forward to working with Chairman Pryor and the other members of this committee on the very important issues facing elderly Americans. Our senior citizens have contributed a great deal to this country; they have made this nation great. We have a responsibility to make sure that, in these volatile times, we give all consideration to their needs and concerns. This issue that we consider today—consumer protection in the hearing aid market—is one that is of major concern to many seniors and I commend the chairman for looking into this important issue.

I'd like to welcome Robin Holm, who is here from Livonia, Michigan on behalf of the International Hearing Society. The Society, which is headquartered in Livonia, represents hearing aid dispensers from all over the United States. I appreciate her willingness to come and tell us about their work and concerns in this area.

I understand the concerns the Food and Drug Administration has raised about insuring that people with hearing impairments get proper care, and I also understand that hearing aid dispensers play an important role in the hearing industry. I'm looking forward to working together to develop a new policy that addresses the hearing needs of people with hearing impairments and maintains an appropriate role for hearing aid dispensers.

PREPARED STATEMENT OF SENATOR ALAN K. SIMPSON

I commend my friends and colleagues Senators Pryor and Cohen for holding today's hearing on problems in the hearing aid industry. Senator Cohen's staff has been particularly involved in examining the issues surrounding hearing loss in older Americans and the hearing aid industry. I want to applaud them for bringing this issue to the attention of the Committee. I understand that the Committee has not held hearing on the hearing aid industry since the early 70's. We are long overdue for another look into the industry, consumer concerns about the industry including misleading advertising, and questionable sales practices of hearing aids, and Government regulation of the industry.

Hearing impairment can seriously affect the safety, and quality of life of older Americans. Older American's purchase almost 65 percent of all hearing aids. However, hearing loss is a disability that we rarely pay attention to unless it affects us

personally or becomes an aggravation when someone we are close to can not hear as well as they used to. It is interesting to note that only 17 percent of the hearing impaired population wears a hearing aid (3.8 million). The most likely reason for this is the lack of reimbursement under Medicare and private insurance policies for hearing aids. Hearing aids can become a very expensive proposition for an older person on a fixed income. That's why it is imperative to look into allegations of improper sales practices and inadequate enforcement of standards in the sales of hearing aids. However, we cannot lose sight of the fact that there are many legitimate manufacturers and dispensers of hearing aids out there and only a few unethical folks can ruin the reputation of an entire industry.

I am particularly concerned about the lack of enforcement by the FDA and State governments in regulating the sales and marketing of hearing aids, and I look forward to hearing testimony from Dr. David Kessler, Commissioner at the FDA. In addition, I am interested in hearing from the AARP on their consumer satisfaction survey and feedback they received from their request for letters on people's experiences with their hearing aids.

I look forward to hearing from today's witnesses and thank the Committee Chairman for holding this hearing today on this important topic.

Senator Simpson submitted questions for witnesses at Aging Committee hearing.¹

DR. MILDRED DIXON, VICE PRESIDENT, AARP

Question. Am I correct in understanding that the AARP sells hearing aids through its pharmacies?

Question. If so, can you tell me if people who bought hearing aids through the AARP were any more or less satisfied than other respondents to your consumer survey?

Question. In your written testimony, you recommended that a 30-day return period should be required for the sale of all hearing aids. Do AARP pharmacies have such a policy and, if so, do they make sure that customers are fully informed that they have the option of returning the hearing aid within 30 days?

Question. What type of "hearing evaluation" should a customer expect to receive at an AARP pharmacy? Are these evaluations always performed by a certified audiologist—as you recommended in your testimony?

Question. When the AARP asked its members to provide "consumer feedback" on hearing aids in the September 1991 issue of AARP Bulletin, was this done in such a way as to elicit responses from all readers or only from those who were dissatisfied?

Question. Can you tell me anything about the nature of the responses the AARP received from my home state of Wyoming? Did the results vary significantly in different regions of the country?

Question. In your written testimony, you stated that only 3.78 million Americans wear hearing aids, but that there are estimated to be 23.5 million Americans with hearing loss. It seems to me that it would be very difficult to make such an estimation unless these people have actually received hearing evaluations. How was the figure of 23.5 million arrived at? Is it based on sound medical evidence or is it mostly speculation?

DR. DAVID KESSLER, COMMISSIONER, FOOD AND DRUG ADMINISTRATION

Question. It seems that the FDA has paid very little attention to the hearing aid industry until the last year and a half. Now we have seven manufacturers who have received warnings from the FDA about their advertising claims. Why the sudden interest? Are their advertising claims less truthful now than they were five or ten years ago? What has changed?

Question. Can you spell out precisely what you would like the manufacturers to demonstrate in clinical trials? What kind of data are you looking for?

PREPARED STATEMENT OF SENATOR DAVE DURENBERGER

Thank you, Mr. Chairman, for holding this hearing today on the hearing aid marketplace. Hearing aids are one of the most widely used assistive devices, and as such, effect a large number of people, particularly the elderly. I welcome the opportunity to explore the concerns of consumers, providers, the industry, and the FDA.

A very small percentage of people who need hearing aids actually have them. Out of approximately 26 million Americans who suffer hearing loss, only 5 million have

¹ See p. 215.

hearing aids. There are many reasons why people do not get hearing aids: vanity, denial, cost, etc. I would hope that anything that we do would not erect more barriers to obtaining hearing aids, given the fact that so few people who could be helped by hearing aids actually have them. At the same time, we want to ensure that hearing aid devices are safe and appropriately dispensed, and that sales standards are met and properly enforced.

We must also consider this issue in a broader context. We are just beginning a process of debating how our health care system will be reformed. Simultaneously, States, providers, and payers are trying to design systems that will provide health care services at lower costs, with an emphasis on prevention, access, and less specialized providers.

We need to be very aware of how changes in this industry will effect health care reforms, costs, and current attempts by States to initiate change before broader health reforms are imposed. Are we limiting or expanding access to care? Are we finding alternatives that will provide care at a lower cost? Are we preserving or improving the quality of the services our current system provides, or losing it altogether?

This is the context in which I believe we should examine this issue, and indeed, any issue related to health care. Thank you, again, Mr. Chairman for this opportunity.

PREPARED STATEMENT OF SENATOR LARRY E. CRAIG

Mr. Chairman, thank you for conducting this hearing concerning the marketing of hearing aid devices. I must admit that when this issue first came up, I was rather surprised because I had not been contacted by any Idahoans expressing concerns or problems in this area. In fact, my experience has been just the opposite. On a personal note, I have known a number of seniors who experienced dramatic improvement in their quality of life by making the decision to purchase a hearing aid device.

As I understand, there have been complaints from some consumer groups that problems do exist. I look forward to hearing those comments, and comments from industry as to what these problems may be, and how they can best be resolved. In looking through some of the material on this issue, there seems to be a need for more information and education on the choice of product, fitting and use—something that the industry appears willing to provide. I am interested to know the witnesses' thoughts on this.

Mr. Chairman, there may be some unscrupulous providers in this industry. Unfortunately, there are unprincipled people in many industries who prey upon consumers. What we must be careful to avoid though, is harming the reputations of the many people who are legitimately providing a valuable service in order to catch the few that are practicing the abuses. Using a broad brush against the hearing aid industry in this issue would be inappropriate.

It seems the best way to insure access to this product and arm the consumer against abuses is to ensure they have the information needed to know what is and is not the product they require.

While there have been some valid claims concerning problems in the hearing aid industry, I would also like us to remember the positive aspects that have improved many people's lives through the services and availability of hearing aid devices. I should again add that I have not heard any negative feedback from my constituents. As a matter of fact, I have received some positive input; and the folks in Idaho are always good about letting me know what's on their minds. It is because hearing devices have helped so many people that I hope the problems that do exist can be readily resolved.

Again, Mr. Chairman, I look forward to the information the witnesses will provide today. I hope we can determine how we can better empower the individual, as a consumer, to restore confidence in making these purchasing decisions.

STATEMENT OF SENATOR WILLIAM COHEN

Senator COHEN. Thank you very much, Mr. Chairman, and I appreciate the support that you have given me and the entire minority staff.

This hearing is really a result of the minority staff's investigation into allegations of misleading advertising and deceptive sales practices by hearing aid manufacturers and dealers, and I hope that this hearing will help us determine if there are sufficient safe-

guards in place to insure that the public, especially older Americans, can purchase hearing aids with full confidence. I want to again thank you for your cooperation in this.

Aging is a universal and natural process that begins at birth and ends at death, and one of the most prevalent health conditions associated with the aging process is hearing loss. Estimates vary, but approximately 30 to 40 percent of adults age 65 and older are hearing impaired, a figure which increases to 50 percent for the individuals who are 75 and older.

In fact, older adults purchase almost 65 percent of all hearing aids, which are third only to canes and eyeglasses as the most widely used assistive devices. This is a major consumer issue for Americans, particularly since hearing aids are not inexpensive, and they are also not covered by Medicare or by most private health insurance plans.

The average retail price of a hearing aid is currently more than \$600, and since many hearing impaired individuals need two aids, the out-of-pocket cost to the consumer can run as high as \$2,500 and more. I am, therefore, extremely concerned that some consumers are purchasing hearing aids they may not need, or hearing aids they cannot use.

Recently, a number of hearing aid manufacturers have come under some fire from the Food and Drug Administration. We're going to hear this morning from FDA Commissioner David Kessler, who will talk about warnings that his agency issued earlier this year to seven major hearing aid manufacturers and distributors whose advertising, promotional, and labeling claims it found to be "misleading and unbalanced."

While all seven manufacturers have since withdrawn the offending materials, I share the FDA's concern that they have created unrealistic expectations for the performance of these products.

For instance, we have an ad that's reflected in Chart 1 for "Miracle-Ear's Clarifier," which claims that the aid "automatically reduces background noise," and "boosts speech, so you can hear more easily what people are saying, even in noisy situations," and, it further claims, that the aid adjusts automatically to the volume of sounds around you, so you can walk from a quiet conversation in one room, into a loud room, without having to manually adjust your hearing aid.

The other ad from "Beltone's Clear Voice," which is on Chart No. 2, claims that the "sophisticated noise-reduction system suppresses annoying background sounds and helps you hear voices clearly, even in crowded places like restaurants, airports, business meetings, and sporting events."

Ladies and gentlemen, hearing aid technology is improving dramatically, but no hearing aid in the world will pick up only those sounds that people want to hear. These ads and others by major manufacturers were misleading, and they're simply not supported by clinical data provided to the FDA.

Further, the ads imply that all people using these particular aids will benefit equally. This is generalization not supported by any scientific data. Hearing loss is an entirely individual matter, and no single hearing aid is right for everyone.

The medical community universally recommends that individuals considering the purchase of a hearing aid be examined by a physician to insure that there are no underlying diseases or medical problems that are causing the hearing loss, because a hearing loss may also be a symptom of another medical problem that needs a doctor's attention. Therefore, the FDA requires hearing aid dispensers to urge consumers to have an examination by a physician before ever purchasing a hearing aid.

Adult patients can, in fact, sign a waiver—a written waiver—of a medical exam, but the dispenser is required to advise them that waiving is not in their best health interest.

This morning, we're going to hear from a number of people who will testify that many hearing aid dealers are ignoring or misrepresenting this waiver to consumers.

An example of the type of cases that have come to the attention of my staff is the case of a legally blind and hearing impaired 92-year-old woman, who received a visit in her home by a hearing aid dealer.

Not only did the dealer fail to advise her that it would be in her best interest to see a physician, he literally put the pen in her hand and put her hand on the signature line, even after she advised him that she could not read the contract. He then filled out her check and helped her sign it.

Mr. Chairman, the minority staff investigation has revealed that far too many elderly consumers are being sold expensive hearing aids they either cannot use or do not need because of the aggressive sales tactics of incompetent, abusive, and fraudulent dealers.

We have to put an end to these practices, both by imposing stricter competency standards and licensing requirements, and by more vigorous enforcement of existing consumer protection laws. Here is a point I'd like to make—it's not that we need more laws. We have laws. They are not being sufficiently enforced in many States.

In some States, all that's required to obtain a license to sell a hearing aid is proof that you are 18, a high school graduate, and of good moral character. If a test is required, it is considered too simple by many experts in the field. In fact, a few States have no requirements whatsoever.

The Committee staff has even heard of instances where untrained apprentices have been fitting and dispensing aids without adequate supervision.

Clearly, all States must take action to raise competency standards through, for example, more stringent testing and certification requirements by establishing requirements for continuing education. We also need to have the State licensing boards, which are charged with enforcing the discipline in the industry, become more varied and representative in their membership, and to become more proactive in protecting the consumers' interests. This is what they're paid to do.

Hearing loss can seriously affect older Americans' safety, their quality of life, and their ability to live independently.

Perhaps my greatest concern is that the kind of problems and abuses we'll hear about today might discourage people who have

experienced a hearing loss from seeking help, and this is just the wrong message to come from these hearings.

We want to encourage people to seek hearing aid assistance.

What we insist upon, however, is that those who are manufacturing, don't engage in either misleading or false advertising, that those who are charged with dispensing the assistive devices, be well-trained, and not engage in abusive and aggressive tactics which take advantage of vulnerable older citizens.

Even though hearing loss can be a natural part of the aging process, too many people—as Senator Pryor has indicated—fail to come to terms with it. No one thinks twice about getting eyeglasses, but there's a reluctance, even a sense of shame, about getting a hearing aid. And while hearing loss may be inevitable for many older persons, technology—when it's appropriately applied—offers a relatively simple solution, and in most cases, that loss is correctable.

This morning's hearing, as the Chairman has indicated, is not about professional turf battles or bashing hearing aid dealers and manufacturers—the majority of whom I believe to be caring and competent professionals—it's about quality of care, about quality of life, and I hope that this hearing will produce the kind of beneficial results that will be of use to many, many people who will be watching the hearings.

Thank you, Mr. Chairman.

The CHAIRMAN. Thank you, Senator Cohen, and I want to thank you and also your staff for the real commitment that you have made to this hearing and also the contribution you've made leading up to this hearing.

I have an announcement; I think it's pretty timely.

We have sound amplification headsets that are available to any member of the audience, or we have audio loops that are available per your request.

The lady right over here is in charge of dispensing these, and I think it takes a driver's license or a credit card to check these devices out. We're not trying to sell them this morning; we want you to know that, but we are going to put them on loan to you.

Senator Kohl from Wisconsin.

STATEMENT OF SENATOR HERB KOHL

Senator KOHL. All right. Well, I thank you, Senator Pryor, and also you, Senator Cohen, for holding this hearing on concerns over possible deceptive practices in the hearing aid industry.

In fact, it was only 1 month ago that I presided over a related field hearing on behalf of this Committee entitled, "Health Care Fraud as it Affects the Aging."

On that occasion, we heard testimony concerning alleged deceptive marketing practices related to other medical devices and services.

I mention this because it represents a disturbing trend that we continue to see in many areas of health care—that being the targeting of our senior population for medical devices they may not need, or devices, in fact, that may not at all work as promised.

The General Accounting Office now tells us that our Nation loses 10 percent of its health care dollars to wasteful practices. Based on

their estimate, we could lose up to \$90 billion of our precious health care dollars this year alone.

Whether these abuses involve hearing aids, prescription drugs, or in-home nursing care, these are practices that simply have to be stopped.

This is not to say that I am making any pre-judgments about today's hearing. Like all of you, I want to listen to the testimony and reserve judgment until the facts are in.

Like so many areas of the health care industry, I am sure that most who deal with hearing problems are caring, honest, and professional people. But there are always a few who desire to make a quick dollar at the expense of those in need of medical help, and especially at the expense of our senior citizens.

I do hope that in the course of deliberating this issue, our Committee and related Federal agencies like the FDA will look carefully at how States deal with these concerns. I can say that in my own State of Wisconsin, we do have a review board within our Department of Professional Regulation, and that board specifically deals with hearing impairment issues.

Unlike many States, the Wisconsin board does include citizen members, so the interests of consumers are represented, and not just those of industry professionals.

I'm also concerned about the possibility of changing FDA rules so that physician exams would be required prior to all hearing aid purchases. Currently, as we know, patients may waive that exam, and I have some worry that making examinations mandatory will only add to the out-of-pocket financial burden of patients, since most hearing aids and exams are not covered through Medicare or other insurance.

I'm also troubled by the concept of just limiting hearing exams to physicians. In Wisconsin, we have strict licensing, testing, and professional competency standards for all hearing professionals, including Hearing Instrument Dispensers, Audiologists, and Speech Pathologists. These are highly trained people who are capable of conducting thorough hearing examinations, and in the rare cases of abuse, our professional review board takes disciplinary action and revokes licenses.

In short, let us look at what some States are doing successfully before we necessarily add more Federal regulation.

Once again, Mr. Chairman and Senator Cohen, thank you for holding this hearing, and I look forward to hearing from the witnesses.

The CHAIRMAN. Thank you, Senator Kohl.

One of our very fine and outstanding members of this Committee—Senator Kohl of Wisconsin, we thank you.

We are going to call our first panelists now. Mr. Miles Kidd and Doris Lomax, would you please come to the witness table?

Senator COHEN. Mr. Chairman, I'm told that Mr. Kidd and our witnesses from West Virginia arrived very late last evening and have not arrived yet this morning. I am prepared to read a statement pertaining to Mr. Hassel Baldwin and also Mr. Bernard Roberts, who will be supportive of Mr. Kidd when he arrives.

The CHAIRMAN. I see. It is my understanding also that it's possible that Ms. Lomax may want to be called upon first.

Is that all right?

Ms. LOMAX. Yes.

The CHAIRMAN. Fine. Ms. Lomax, we would like to hear from you now.

STATEMENT OF DORIS H. LOMAX, TAMPA, FL

Ms. LOMAX. Thank you.

The CHAIRMAN. We appreciate you coming, by the way. On behalf of the Committee, we thank you very much.

Ms. LOMAX. It's an honor, and I want to thank the Committee for inviting me to testify here today about my experiences as a consumer tester in a hearing aid shopping test.

My name is Doris Lomax. I am a 65-year-old widow living alone in Tampa, Florida. I'm a retired licensed practical nurse, currently doing volunteer work for Catholic charities and the Senior Companion Program.

Because my income is relatively low, I need to watch my expenses very carefully. My rental payment is subsidized under Section 8 of the Housing Program.

Last fall, I participated in a volunteer hearing aid shopping test commissioned by the American Association of Retired Persons. I was recruited by Dr. Margaret Wylde of the Institute of Technology Development in Oxford, Mississippi.

Dr. Wylde is an audiologist who tested my hearing, and spent a day training all the consumer testers in preparation for what they called "the shopping experience study." I cannot describe the overall findings of the AARP study, but I can describe what happened to me.

During September and October of 1992, I visited 11 different hearing aid sales facilities in Tampa. Most of the people who examined my hearing were hearing aid specialists. At other sites, an audiologist examined me.

There were two of us who visited each site as a team. Only I had my hearing checked at each site, but both of us wrote down what happened after each visit.

When I started this project, I had no idea what to expect. Back then, I would have simply looked in the Yellow Pages under hearing aids for the nearest location.

After visiting 11 hearing aid sales operations and learning what is required, I wouldn't go back to have my hearing checked at most of these sites. In general, they seem to be more interested in selling me an aid than considering my situation and me as a person.

The prices quoted to me for aids ranged from \$550 to more than \$3,500 for two.

I do have a slight hearing loss. My condition is what is called a mild frequency loss, and I am a borderline candidate for a hearing aid. An aid might help me, but the expense is considerable, given the fact that I don't have a lot of difficulty in hearing.

I have no trouble talking on the phone, and can hear most conversations. The only difficulty I have is hearing in a noisy condition.

My 11 hearing evaluations varied in length from 20 minutes to an hour and 20 minutes. Based on the training we received, I knew exactly what tests should have been conducted.

The State of Florida specified what should take place in a hearing aid evaluation. I was surprised at the number of practitioners who didn't follow these procedures.

At two sites, my audiometric evaluation consisted of only pure tone air tests. Both pure tone air and bone tests are required, but the bone test wasn't provided. At three facilities recommending I buy an aid, I was not provided all the other required tests.

At all but three sites, a soundproof booth was used for audiometric testing. In two of the remaining three sites, a quiet room was used.

At one facility; however, there was no soundproof booth, and even though the room was called a quiet room, it wasn't. I couldn't hear the test tones for the noise of passing traffic, car horns, telephones ringing, the air conditioner, and people talking.

I complained about this to the evaluator, and he answered, "You are not going to use your aid only in a quiet room are you?"

Only 3 of the 11 evaluators recommended that it was in my best interest to see a doctor before buying an aid.

There were eight evaluators who I felt were honest with me. Three told me I didn't need an aid, five said, "Yes"—that I do have a small loss, but given my financial situation, an aid may not help that much. They would sell me one if I wanted it, but they recommended that I come back in a year to be retested.

Three practitioners told me I needed an aid right now, if not sooner. One salesman was a factory representative who was only there for 1 day. He offered me a 20-percent discount on a pair of hearing aids that sold for \$3,500 if I bought them then.

Another told me my right ear canal was collapsing, and that I needed an aid right away to correct that condition. It's interesting that no other evaluator found this condition, nor did Dr. Wylde in her otoscopic examination.

I am told that even if my canal were collapsing, there were far less costly remedies than buying an aid.

Seven facilities offered free hearing tests. I was instructed to ask for a copy of my audiogram at each site. A dispenser at one of these sites told me I could have a copy of my test results only if I paid \$25.

Because of my limited income, I told one dispenser that I would have difficulty paying \$500 or more for an aid. I was told that it didn't make any sense to buy a cheap hearing aid; it would only end up in my dresser drawer, and I needed the more expensive aid.

Another facility was involved in what I believe to be a "bait and switch" operation. When I was tested, I was told I needed a \$500-\$600 aid.

Within days of my exam; however, this facility ran an ad in the paper with a \$249 hearing aid. I called and asked why I wasn't offered this aid. The answer was, the cheaper aid wouldn't work for me because it only amplified a little bit.

One audiologist tested my hearing, and quoted me a price of \$50 for the test. However, she also performed what is called a tympanic test, and added \$15 to the cost without telling me of it.

Thank you, again, for allowing me to share my experience with this Committee. I'd be happy to answer questions.

[The prepared statement of Ms. Lomax follows:]

Statement of
Doris H. Lomax
Tampa, Florida
Consumer Tester

I want to thank the committee for inviting me to testify here today about my experiences as a consumer tester in a hearing aid shopping test. My name is Doris H. Lomax and I am a 65 year old widow, living alone in Tampa, FL. I am a retired Licensed Practical Nurse currently doing volunteer work for Catholic Charities and a program called Senior Companion. Because my income is relatively low, I need to watch my expenses very carefully. My rental payment is subsidized under the Section 8 housing program.

Last fall I participated in a volunteer hearing aid shopping test commissioned by the American Association of Retired Persons. I was recruited by Dr. Margaret Wylde of the Institute of Technology Development (ITD) in Oxford, MS. Dr. Wylde is an audiologist who also tested my hearing and spent a day training all the consumer testers in preparation for what they called a shopping experience study. It is my understanding that AARP is releasing a report containing the overall results of this study later in this hearing. I cannot describe the overall findings, but I can describe what happened to me.

During September and October of 1992, I visited 11 different hearing aid sales facilities in Tampa. Each site was different. Most of the people who examined my hearing were what are called hearing aid specialists. At the other sites, an audiologist examined me. There were two of us who visited each site as a team. Only I had my hearing checked at each site, but both of us wrote down what happened after each visit.

When I started this project, I had no idea what to expect. Back then, I would have simply looked in the Yellow Pages under hearing aids for the nearest location. After visiting 11 hearing aid sales operations and learning what is required, I wouldn't go back to have my hearing checked at most of these sites. In general, they seemed to be more interested in selling me an aid than considering my situation and me as a person. The prices quoted to me for aids ranged from \$550 to more than \$3500 for two.

I do have a slight hearing loss. My condition is what is called a mild high frequency loss and I'm a borderline candidate for a hearing aid. An aid might help me, but the expense is considerable given the fact that I don't have a lot of difficulty in hearing. I have no trouble talking on the phone and can hear most conversations. The only difficulty I have, is hearing in a noisy conditions.

My 11 hearing evaluations varied in length from 20 minutes to an hour and 20 minutes. Even without, in a number of instances, conducting all the required tests, eight of the 11 practitioners recommended that I need an aid. Five of these indicated it was up to me whether or not I needed an aid. Three said I needed an aid right away.

Based on the training we received, I knew exactly what tests should have been conducted. The state of Florida specifies what should take place in a hearing evaluation. I was surprised at the number of practitioners who didn't follow these procedures. For example, in one site, the evaluator never examined my ears with an otoscope. He wouldn't know if I had too much ear wax or even possibly a medical problem.

At a second site, the evaluator used a pen light to examine my ears not an otoscope. When I say pen light, I mean something you can buy at any drugstore.

At two sites, my audiometric evaluation consisted of only pure tone air tests. Both pure tone air and pure tone bone tests are required but the bone test wasn't provided. I didn't ask why this test or others wasn't provided because I didn't want the evaluator to become suspicious about me. I was instructed to act like a naive, first-time buyer.

At three facilities recommending I buy an aid, I was not provided all the other required tests such as speech discrimination, speech recognition, and most comfortable loudness even though they recommended an aid to me.

In only a few instances did the evaluators explain to me what was going on or why each test was important. To find out anything, I always had to ask questions. I guess each buyer must determine for himself/herself why such tests are important.

At all but three sites, a sound proof booth was used for audiometric testing. In two of the remaining three sites a "quiet" room was used. At these two sites, the room actually was quiet and I could hear the electronic tones. At one facility, however, there was no sound proof booth and even though the room was called a "quiet" room, it wasn't. I couldn't hear the test tones for the noise of passing traffic, car horns, a telephone ringing, the hum of an air conditioner, and people talking. I complained about this to the evaluator. He answered "you're not going to use your aid only in a quiet room, are you?"

Only three of the 11 evaluators recommended that it was in my best interest to see a doctor before buying an aid. The other eight never even raised the question.

Finally, let me discuss some of the statements made to me by these hearing evaluators. Two practitioners told me an aid was unnecessary at this time. Five recommended an aid but left it up to me to decide if I really needed one but that I should continue to monitor the situation and come back in a year for further tests.

Three practitioners told me I needed an aid right now if not sooner. One salesman claimed he was a factory representative who was there only for the day. He offered me a 20 percent discount on a pair of hearing aids that sold for \$3500.

Another told me my right ear canal was collapsing and that I needed an aid right away to correct that condition. It's interesting that no other evaluator found this condition, nor did Dr. Wyldie in her otoscopic examination. I am told that even if my canal were collapsing, there are far less costly remedies than buying an aid.

Seven facilities offered "free" hearing tests. I was instructed to always ask for a copy of my audiogram at each site (an audiogram is a record of my hearing levels at different frequencies). A dispenser at one of these sites told me I could have a copy of the audiogram only if I paid \$25.

At one site, the examiner was different from the salesman who saw me after the evaluation. The salesman said he was a factory rep who was on site that day. He told me I needed two hearing aids right away and had to place the order that day because he, the factory rep, wouldn't be back for three months.

The cost of each aid was \$2000 but he could get me two for \$3500 and a 20 percent discount on top of that if I bought that day. Both of these aids are what are called programmable aids.

Because of my limited income, I told one dispenser that I would have difficulty paying \$500 or more for an aid. I was told it made no sense to buy a cheap hearing aid. It would only "end up in your dresser drawer." You need the more expensive aid.

Another facility was involved in what I believe to be a "bait and switch" operation. When I was tested, I was told I needed a \$500 to 600 aid. Within days of my exam, however, this facility ran an ad in the paper with a \$249.50 hearing aid. I called and asked why I wasn't offered the cheaper aid. The answer was, the cheaper wouldn't work for me because it only amplified a little bit.

Few of the evaluators offered me a trial period with a new aid unless I asked for it. When I asked, most offered some form of trial but each seller was different. Some offered to refund all but \$75 to \$100. Others said they would refund some money. Some also said they weren't worried about a refund because they were sure I would like the aid.

One audiologist tested my hearing and quoted me a price of \$50 for the test. However, she also performed what is called a tympanic test and added \$15 without telling me that in advance.

There were eight evaluators who I felt were honest with me. Three told me I didn't need an aid. Five said that yes I do have a small loss, but given my financial situation, an aid might not help that much. They would sell me one if I wanted but they recommended I come back in a year to be retested. If at that time the need is greater, they'd be happy to sell me one.

My advise to first-time buyers: Be careful. I recommend that consumers visit a physician's office (ENT) to have their hearing checked. At these sites, a doctor can check your ears, and there's almost always an audiologist on staff to evaluate your hearing. Second, ask questions about what is happening. What do the tests results show? Is there a free trial period, and what kind of warranty is provided?.

Thank you again for allowing me to share my experience with this committee. I'd be happy to answer any questions.

The CHAIRMAN. Ms. Lomax, we really appreciate you coming this morning. You've had quite an experience here, and we also appreciate you going to those 11 separate sites and sharing this information with us, and also AARP for sponsoring those visits.

Your confidence level seems not to be very high at this point.

Ms. LOMAX. No. It isn't.

The CHAIRMAN. Relative to the purchase of a hearing aid and being tested to see if an individual actually needs a hearing aid.

Did you have the opportunity to ask any of the hearing specialists that you dealt with about their training or their educational background?

Ms. LOMAX. One that I can remember—I was told by a young man that he was in training—that he could be trained on the site if the head man was an audiologist. And he was the one that performed the test, and the audiologist wasn't there.

The CHAIRMAN. And which of the people told you that—I believe—was it your eardrum was collapsing, or the canal?

Ms. LOMAX. The wall of the ear canal was collapsing.

The CHAIRMAN. And who was that? Was that a specialist, or was that a hearing aid salesperson?

Ms. LOMAX. A specialist.

The CHAIRMAN. Now did you actually see a difference in the attitude of those people who were selling hearing aids, versus those people who were actually trained to test for any impaired hearing?

Ms. LOMAX. Yes. Yes. There was definitely a "hard sell" atmosphere with most of them. And it had to be done right away.

The CHAIRMAN. Ms. Lomax, did you feel at any time that because—one, you are elderly, and two, that you are somewhat alone and perhaps vulnerable, that someone was attempting to take advantage of you?

Ms. LOMAX. I really wasn't alone; I had someone with me. And I was sure that they were taking my age into consideration.

At one point, I told one of the testers that I needed the information to give to my son; he was going to purchase me a hearing aid.

They just said, "Well, why isn't he here then if you're going to give it to him?" And I said, "Well, maybe it's because he's in Atlanta."

That's where he lives. So that was, I thought, uncalled for.

The CHAIRMAN. But whether you like your position or not, you're now one of the foremost authorities in America on buying hearing aids and being tested.

Ms. LOMAX. Well—

The CHAIRMAN. We're very proud of you.

What advice would you give right now to people who may suspect some hearing loss or—what advice would you give to people right now in contemplating the ultimate purchase of a hearing aid or getting some assistance to better their impaired hearing?

Ms. LOMAX. The thing that I would do if it were affordable is go to a physician—an ear, nose, and throat doctor—where I'd be sure that he knew exactly what he was doing, and get the examination.

They usually have an audiologist right on the job who does the testing and then if she had seen my collapsed ear wall, she could have consulted the physician right then. And I would feel that I was getting a chance to have a better fit and a better aid.

The CHAIRMAN. All right. I'm going to yield to Senator Cohen at this time. Thank you.

Ms. LOMAX. Thank you.

Senator COHEN. Ms. Lomax, what would you do if you couldn't afford it?

Ms. LOMAX. I would do without.

Senator COHEN. Rather than go to a nonspecialist or a nonphysician, you would recommend to others who might be watching, who might have some hearing impairment, that they would be better off going without than with seeking—

Ms. LOMAX. No. I would think it would be according to what their problem was.

In my case, it wasn't absolutely necessary, so I have started a little savings myself to work up to the point where I can go back and hopefully get what I need.

Senator COHEN. You come with some special qualifications—you're a nurse. Right?

Ms. LOMAX. Well—

Senator COHEN. A retired nurse. And yet with your medical background, when you started out looking for a hearing aid, I think you've indicated you would have gone to the "Yellow Pages."

Ms. LOMAX. Probably, because I had never considered what was involved in getting a hearing aid.

Senator COHEN. And I think most people would probably do the same thing.

Ms. LOMAX. I would think so, or word of mouth.

Senator COHEN. Right. And they may see an ad on television.

Ms. LOMAX. Yes.

Senator COHEN. Or in the newspaper.

Ms. LOMAX. Yes.

Senator COHEN. Or one of the magazines, and say, "It looks like something for me."

So what I'm asking is, many people may not be able to afford to go to a physician—

Ms. LOMAX. True.

Senator COHEN. There are quite a few areas, in Wisconsin, and Arkansas, and Maine, where specialized physicians might not be available. They are in rural areas in which they don't have a specialist—

Ms. LOMAX. True.

Senator COHEN. Ear, nose, and throat physicians—and what do they do at that point? What would you recommend?

Ms. LOMAX. Well, if they have any way of getting any information on how to buy one, to do that first. Right now, it's not really that available.

And second, I would probably just walk into a place and see what they have to offer. If they would learn to ask questions—you could find a lot of people who are qualified—more than qualified—if you can find out what questions to ask them.

Now none of the people that I visited offered any information on warranties unless I asked them. None of them ever said that there was a place where you can file complaints, and I had to ask them all about the trial periods. They never volunteered any of this information.

Senator COHEN. Does Florida require a 30-day trial period?

Ms. LOMAX. Yes. I was told that it's one of their laws, but they still never offered it unless you asked.

Senator COHEN. So basically, it's the responsibility of all of us—AARP, this Committee—to get out information to the elderly consumer—

Ms. LOMAX. To educate the consumer.

Senator COHEN. About the kinds of questions they should ask—

Ms. LOMAX. Yes. That's true.

Senator COHEN. If they don't have the resources to go to a specialized physician and they choose to go to a nonspecialist, such as a hearing aid distributor, they should know the types of questions that they should be asking and the answers they should insist upon.

Ms. LOMAX. I think that's very necessary—very necessary.

Senator COHEN. Well, Ms. Lomax, thank you very much. You've been very helpful in presenting your testimony.

Ms. LOMAX. Thank you. Thank you for having me.

Senator COHEN. Thank you very much.

The CHAIRMAN. Senator Kohl.

Senator KOHL. Thank you very much, Senator Pryor.

Ms. Lomax, I just want to read again one brief paragraph from my statement and ask you your comment on it.

Ms. LOMAX. Yes?

Senator KOHL. I said that I was troubled by the concept of just limiting hearing exams to physicians.

I said that in Wisconsin, we have strict licensing, testing, and professional competency standards for all hearing professionals, including hearing aid salespeople, audiologists, and speech pathologists.

I said that these are highly trained people who are capable of conducting thorough hearing examinations, and that in the rare cases of professional abuse, we have a professional review board, which takes disciplinary action and revokes licenses.

Would you suggest that we have this kind of system in place in all 50 States?

Ms. LOMAX. It sounds to me like we need it in all 50 States, from what I have seen, and I think it would be one of the greatest things that could happen—is to have a lot more—we can make laws, but if you don't enforce them, they aren't worth anything.

Senator KOHL. Yes.

Ms. LOMAX. Florida has laws, but there is apparently no one there to check on what's going on.

Senator KOHL. Yes.

Ms. LOMAX. And I think that's one of the greatest needs we need—good laws and then follow up on the laws.

Senator KOHL. Well, I thank you, Ms. Lomax.

Ms. LOMAX. Thank you.

Senator KOHL. Thank you, Mr. Pryor.

The CHAIRMAN. Thank you, Senator Kohl.

Our friend from Vermont has just arrived, Senator Jeffords.

We're proud that you're here with us this morning, and wonder if you have a statement. This is Ms. Lomax.

Senator JEFFORDS. Good morning.

The CHAIRMAN. She's been to 11 different sites, looking at hearing aid dealers.

Ms. LOMAX. Good morning.

The CHAIRMAN. Trying to decide if she has a hearing impairment. Also, she's come across with some, I think, fairly unscrupulous people who attempted to pressure her into buying hearing aid devices, so she's been a fine witness.

If you have any questions or desire to make a statement, we'll call on you.

STATEMENT OF SENATOR JAMES JEFFORDS

Senator JEFFORDS. Thank you, Mr. Chairman. I do have a statement, which I'd like to make part of the record.

The CHAIRMAN. Without objection, your prepared statement will appear in the record.

[The prepared statement of Senator Jeffords follows:]

PREPARED STATEMENT OF SENATOR JAMES M. JEFFORDS

Mr. Chairman, I am most pleased to participate in the proceedings this morning concerning the hearing aid marketplace. This issue has been explored by Congress and the Executive Branch a number of times in recent years but obviously important questions remain. Now that the Administration appears committed to overall health care system reform, I think it most appropriate that we turn our attention today to the important hearing aid component.

I have two special reasons for paying particular attention to the testimony of our witnesses today, all of whom I thank for attending and giving their time.

The first is strictly personal. While serving in the U.S. Navy after my college days my ears took a heavy pounding from the noise the big guns made during readiness drills. So much so that over the last several years I have noticed, and my doctors have confirmed, a significant hearing loss in my left ear. I am to be fitted with a hearing device soon to see if some of the loss can be corrected.

So you can see that the questions to be raised today about hearing impairment, quality of life, marketing of hearing devices, cost and need for medical or other evaluation are not academic in my case. I know the importance of good hearing and of access to competent and reliable hearing care givers. I have unimpeachable credentials, even though I might not be entirely happy about it!

The second special interest I bring today relates to the pivotal role that my State of Vermont has been playing in the hearing device delivery area. As most of you know, under FDA regulation, a buyer must be urged to have an examination by a physician before purchasing a hearing device and the dispenser of the device must obtain a written statement from the purchaser that a medical examination has been urged upon him or her. However, a patient has the right under the FDA regulation to avoid any actual medical examination by simply signing a written waiver.

In 1989 Vermont passed a law which requires, among other things, a physician evaluation for all first-time purchasers of hearing aids, without any possibility of waiver. The law was passed because the Vermont legislature found that the waiver provision of the FDA regulation was being abused and that too many patients were receiving hearing aids without appropriate medical evaluation. In July of 1989 the Vermont Attorney General requested an exemption from the FDA regulation, so that the State could avoid Federal preemption and allow its stricter law to go into effect.

This "Vermont petition", as it has come to be called, has not yet been acted upon by the FDA, in spite of the fact that over four years have elapsed. This might be a positive sign in view of the fact that earlier petitions by six other States were denied. Nevertheless, I think the time has come for action. Happily I am informed that the FDA is now preparing to act on new regulations, that may in fact move towards the Vermont position. I am greatly looking forward to any affirmation or clarification that Commissioner Kessler might be able to give us today.

I am very proud that Vermont is out front on this important issue. Nevertheless I realize that valid questions remain. For example are medical doctors the only professionals who should be qualified to make evaluations for purposes of hearing aid dispensation? Will the cost involved in an evaluation, particularly a medical evalua-

tion, be too great an impediment to access to hearing aids for some people? Should allied health professionals be used to supplement the doctors, particularly in rural areas such as Vermont where access to medical doctors can sometimes be difficult.

These are some of the questions I hope we can address today. Others concern the cost of hearing aids and whether this cost should be covered by Medicare or private insurance policies as they almost always are *not* today. Misleading advertising resulting in inappropriate care is still another.

As we can see these questions parallel closely the questions this Nation must wrestle with as it undertakes overall health care reform. In the hearing aid arena, as in the broader health care arena, the basic query must be: Is appropriate care getting to the people who will benefit from it most in an efficient and reliable manner?

I look forward to today's hearing giving us more insight into the answer or answers to that question as applied to hearing aid devices.

Thank you.

Senator JEFFORDS. I am also looking for a hearing aid, so I'm here to listen to those who have had trouble.

I know, our State of Vermont has been very active in this area, in trying to prevent abusive people—who are looking for them and trying to control it, so I am here to listen.

And due to my late arrival, I will not interfere with the process by asking any questions.

The CHAIRMAN. Well, we very much appreciate your participation with us.

I'm going to call now—if there are no further questions for Ms. Lomax, I'm going to—we are indebted to you.

And by the way, would you like to remain at the witness table? Ms. LOMAX. Sure.

The CHAIRMAN. We may find another question or two—

Ms. LOMAX. Sure. Thank you.

The CHAIRMAN. And we'll just ask you to share the witness table with our next witness, Mr. Miles Kidd.

Mr. Kidd, could you come forward, please?

Mr. Kidd is an 81-year-old retired school teacher from Kanawha County, West Virginia.

He went in for a simple, free hearing test—he thought it was simple, and he thought it was free. While he was there, sales personnel pressured him into buying a \$1,000 hearing aid, and it was of no assistance to Mr. Kidd.

He was only able to get some relief after he contacted and enlisted the help of the Attorney General of West Virginia.

We will hear from the Attorney General's Office in a few moments, but now, Mr. Kidd, we would enjoy very much your stating what happened to you. We thank you for appearing before our Committee this morning.

Mr. CARBONE. Senator, if I may, my name is Jim Carbone. I'm an Assistant Attorney General with the West Virginia Attorney General's Office.

The CHAIRMAN. Very good, sir.

Mr. CARBONE. I'm here to assist Mr. Kidd if necessary—

The CHAIRMAN. Wonderful.

Mr. CARBONE. And as you said, our Director will be testifying later about his investigation and enforcement actions against hearing aid dealers.

The CHAIRMAN. Well, we appreciate what you did for Mr. Kidd, and also your coming to be with him.

Thank you.

STATEMENT OF MILES KIDD, KANAWHA, WV

Mr. KIDD. Mr. Chairman, and members of the Special Committee, my name is Miles Kidd. I am pleased to be here before you to discuss my experience in purchasing a "Miracle-Ear Hearing Aid" from a former "Miracle-Ear" dealer located in Charleston, West Virginia.

I am an 81-year-old retired school teacher from West Virginia. I am a widower, and I have been living on a fixed income since retirement in 1976.

Several years ago, my daughter saved a newspaper advertisement promoting the virtues of "Miracle-Ear" brand hearing aids, and offering a free hearing test. My daughter knew that I had been having trouble hearing, and she encouraged me to make an appointment for a hearing examination.

I noticed that I had been having hearing problems. While I can hear fairly well, I have difficulty discriminating between sounds that are similar, such as D, C, and B.

Consequently, I decided to make an appointment for a free hearing test with the "Miracle-Ear" dealer of the Charleston, West Virginia office.

Upon entering the "Miracle-Ear" dealer's office for my appointment, my initial impression was that the people treating me were very anxious to sell me a hearing aid. The hearing aid dealership employees raced to my side, and attempted to make me feel comfortable by engaging me in "small talk."

Next, the receptionist asked me a series of questions relating to the history of my hearing impairment. When I told the receptionist that I had recently experienced dizziness and light-headedness, the receptionist impassively proceeded with the next question on her list and did not seem to be concerned.

I was then ushered into the office of a hearing specialist and placed inside a booth to undergo a hearing test.

Prior to testing my hearing, the hearing specialist never informed me that it would be in my best interest to have a medical evaluation by a licensed physician that specializes in ears and hearing problems.

In addition, I do not recall signing a waiver relinquishing my right to have a medical evaluation to be tested for a hearing aid.

After the hearing test was concluded, the hearing specialist and his assistant subjected me to high pressure sales tactics designed to convince me to purchase a hearing aid.

First, the specialist and the assistant stated that the test showed that I had a significant hearing loss that necessitated my purchase of two hearing aids. In like form, the specialist and the assistant stated that it was necessary for me to purchase two hearing aids in order to adequately detect the direction from which sounds were coming.

Second, the specialist and the assistant stated that I would eventually lose all my hearing if I did not purchase the hearing aids.

Naturally, I assumed that the individuals testing my hearing were skilled in the hearing profession and were being honest with me.

Of course, I was born in an era when you were taught to take people at their word.

I succumbed to the sales pressure and decided to purchase just one hearing aid from "Miracle-Ear" for the price of \$975. The money used to pay for the hearing aid was a good portion of my checking account.

Immediately after purchasing the hearing aid, I began to have problems hearing. The hearing aid dulled the sound and proved to be more of a hinderance than a benefit to my hearing condition. In fact, I could hear better without the hearing aid than when I was wearing the hearing aid.

When contacting the dealership and expressing my dissatisfaction with the hearing aid, the dealership just gave me excuses, stating that I merely had to get used to wearing the hearing aid.

After giving the dealership numerous attempts to repair the hearing aid, I finally gave up and put the hearing aid in my desk drawer. I felt hopeless and did not know where to turn.

In June 1992, I read an article discussing the Attorney General's investigation of the "Miracle-Ear" dealership from which I had purchased the hearing aid. I decided to contact the West Virginia Attorney General's Office and issue my complaint against that hearing aid dealership.

Upon receipt of my complaint, the Attorney General's Office stated that the dealership had violated my consumer rights in the following respects:

First, breached expressed and implied warranties in connection with the sales of hearing aids;

Two, violated my right to cancel the hearing aid purchase agreement;

Three, failed to comply with Federal and State preconditions to the sale of the hearing aid by not referring me to a physician or hearing and ear specialist prior to fitting my hearing aid; and

Four, engaged in high pressure, coercive sales tactics.

Through the determined efforts of the Attorney General's mediation staff, particularly Melissa Frerichs, I was able to obtain a refund of \$850 from Dahlberg, the manufacturer of my "Miracle-Ear" brand hearing aid.

Since my troubling experience with the "Miracle-Ear" hearing aid and the dealership, I have not had the courage to purchase any other hearing aids, although I recently had my ears examined by an audiologist, who discussed my hearing loss at length and gave me no false hopes or promises.

While I don't believe I will ever purchase another hearing aid, I often wonder what life would be like if I didn't have to constantly worry about my being able to hear and understand simple, ordinary human conversation.

I thank you. That is the end of my testimony.

The CHAIRMAN. Mr. Kidd, that was a beautiful testimony. It was eloquent, and we are very grateful for you coming here this morning—we're grateful to you, I should say.

I have only one question. I just want to make certain that I understood your testimony.

Did you actually request, or did the specialist that you were talking to give you any advice about consulting a physician who is qualified to test your hearing? Was that discussion ever given or had?

Mr. KIDD. I'm sorry, I didn't quite get that question.

The CHAIRMAN. Yes, sir.

Mr. CARBONE. Mr. Kidd indicated to us that he talked to the receptionist. They had given the responsibility to ask really important questions to the receptionist.

He indicated that he experienced dizziness, and she brushed that aside, you know, and she just went on to the other questions, so he said at no point was he verbally told that it was in his best interest to see a medical doctor.

Also, he stated that he never signed a waiver, at least to his understanding. And we subpoenaed the records, and we didn't see a waiver in the files.

The CHAIRMAN. And also, I might just ask you, sir, this question. He did attempt to get his money back and he was refused that request at first, is that correct?

Mr. CARBONE. Yes. The dealership refused his request. Dahlberg paid him everything except the fitting fee, which was \$125, through mediation efforts.

The CHAIRMAN. Fine.

I'm going to yield to Senator Cohen.

Senator COHEN. Mr. Chairman, as you indicated, Mr. Kidd provided some very poignant testimony. He obviously was very nervous as well—not being a professional witness—to come before the Committee. He has been accompanied by two other individuals who had similar experiences, and I'd like to just give the Committee some idea of the nature of the problems that other citizens have encountered as well in his area.

He's accompanied by Mr. Hassel Baldwin, a 78-year-old retired coal miner, who's on black lung disability and Social Security.

It's my understanding that Mr. Baldwin, who has some hearing impairment, saw an ad on television for a free test, and he called the number on the screen. A representative from a "Miracle-Ear" dealer in Charleston came to the house and tested Mr. Baldwin in the living room and told him he needed, as they did to Mr. Kidd, two hearing aids.

Mrs. Baldwin, his wife, explained that they could only afford one, and they bought it for \$800, after borrowing some money to make a \$200 downpayment.

The West Virginia Attorney General's Office has told us that the person who tested Mr. Baldwin was a trainee, and that unbeknownst to Mr. Baldwin, he signed an agreement to finance the payments at a rate of over 27 percent.

He was never informed that it would be in his best interest to see a physician, his demands for servicing of the poor-fitting hearing aid were never adequately responded to, and the testing was done improperly—all in violation of both the Federal and State requirements.

We also have, in the audience today, Mr. Bernard Roberts, who's an 84-year-old retired social worker who has 10 grandchildren and is from Merne, West Virginia. He had owned a pair of hearing aids for about a year when he went to the "Miracle-Ear" dealer in Charleston to purchase batteries.

While he was there, a sales representative convinced him that he needed a new set of hearing aids that were far better than the ones

he owned, and after a rather high pressure sales presentation, Mr. Roberts went to the bank and borrowed the money to pay \$2,820 for the new aids.

Not long after one of the aids started having problems, he went back to the store to have them fixed, and according to the West Virginia Attorney General's Office, was given another one out of the drawer in the store that was not custom-fitted.

Mr. Roberts has paid off his loan of almost \$3,000, and the "Miracle-Ear" hearing aids now sit in a drawer in his house. He's back to wearing the original ones that he had purchased, which he was told were rather outdated.

These are two additional cases from two people who are here to lend additional substance to what Mr. Kidd has testified to very poignantly, today.

I want to take this opportunity to thank Mr. Carbone from the Attorney General's Office for assisting the Committee in bringing this to our attention.

Mr. CARBONE. Well, thank you for inviting us.

Senator COHEN. I think, as Senator Kohl has indicated, we're not trying to single out any particular dealer or manufacturer, but to the extent that we have salespeople who are engaging in this type of activity, we have an absolute obligation to call attention to the types of tactics that are being used in order to inveigle as much as \$3,000 dollars, and more, out of people who really are very vulnerable to that type of tactic.

One question, Mr. Kidd—if you had the chance to do this all over again, would you respond to a newspaper ad that advertises a free hearing test?

Mr. KIDD. I very seriously doubt that, sir. I think if I were doing it over again, I would go to an ear specialist to begin with.

Senator COHEN. Now you also stated that you do not have the courage now to purchase any other hearing aids. Do you believe if you had the courage to wear them again, and you had people who you could rely upon—you've had the assistance of the Attorney General's Office and you now have the attention of the highest officials in West Virginia—would they not be in a position to recommend you to specialists to help you acquire the kind of hearing assistance from whatever dealer you might need?

Mr. KIDD. They, of course, would be reliable and would know what they were doing. Yes, I expect I would rely on what they would tell me.

Senator COHEN. Well, Mr. Chairman, I hope as a result of this hearing that the many elderly citizens who are watching this, and may be suffering from some kind of hearing impairment learn from Mr. Kidd. I think many of us are approaching the age that we do suffer some loss. I know that I have my own problems, and my parents—or at least, my father, who refuses to admit it—have a hearing impairment as well—

The CHAIRMAN. I hope he's not watching this morning on T.V.

Senator COHEN. Well—I hope he is watching.

When I tell him he is going deaf, he responds, "I'm not deaf, I'm just a little hard of hearing."

In any event, I hope that the people watching will take some comfort in the fact that there are laws on the books, and that there

are sincere dealers, with practicing specialists that are professional, who do conduct themselves in an unabusive way.

We want to make sure that the people are in a position to discriminate properly between those who are professional and those who are not. It's going to require quite an educational effort on our part, from the senior citizen community, from this Committee, from various Members of Congress to get the word out to those who are vulnerable to either misleading tactics or aggressive sales promotions, that they can turn to people in their State and get the kind of relief that's necessary. We certainly don't want to discourage people like Mr. Kidd, who does need some hearing assistance, from acquiring that assistance. We want to make sure that you get the help you need.

So this hearing, I hope, will clarify that for everyone. We need to have truth in advertising, we have to have responsibility in the field, and we have to have trained personnel who tell the consumer what they need to know, and hopefully, that the consumer can rely upon that information. That does not appear to be the case in every respect today.

We don't want to indict on a general scale, either the manufacturers or the distributors or the audiologists or the specialists, but rather to insist that they measure up to the responsibilities that we assume that they have undertaken.

Mr. Kidd, thank you for coming. I know that you've been nervous. I know it's been a long trip for you to come here and you arrived late, but we appreciate very much the testimony you've given.

Mr. KIDD. I thank you, sir, very kindly, and the Committee. I thank everyone involved very kindly.

Senator COHEN. Thank you.

The CHAIRMAN. Let's see if Senator Kohl has a question.

Senator KOHL. Oh, thank you very much, Mr. Chairman.

Mr. Kidd, I think your testimony has been just beautiful and instructive and helpful to us, and we all appreciate the effort to which you've gone to get here today and to tell us about what happened to you.

I'm sure it's going to benefit this Committee as it proceeds in trying to get in place and enforce the kinds of safeguards that you know we need in this field, so I thank you for coming here today.

Mr. KIDD. I thank you all.

The CHAIRMAN. Mr. Kidd and Ms. Lomax, you've both performed a real public service today by coming, and it's not easy to share these personal experiences out in public and in front of all the cameras and the people in the audience, but we are indebted to you, and I know that many people across our country are going to be indebted to you also because it may prevent them from getting into same or similar circumstances that you found yourself in.

We are indebted to you, and we thank you. You're excused.

Ms. LOMAX. Thank you.

The CHAIRMAN. Mr. Attorney General, we thank you also.

Mr. KIDD. I thank you all very kindly again.

Ms. LOMAX. Thank you very much.

The CHAIRMAN. Thank you.

We're going to call our next witness now. He is certainly no stranger to testifying on Capitol Hill.

Dr. David Kessler is the Commissioner of the Food and Drug Administration, commonly known as FDA. He is, without question, the force behind all strategic initiatives that are implemented under the FDA mandate to protect public health and to insure consumer protection.

Dr. Kessler, I want to apologize to you for a few moments. I'm going to go upstairs to the other hearing that I mentioned, and my colleagues, Senator Cohen and Senator Kohl, are going to participate, and I'm going to try to get back before you finish.

I'll be returning very soon. We are very indebted to you for coming.

STATEMENT OF DAVID KESSLER, M.D., COMMISSIONER, FOOD AND DRUG ADMINISTRATION, ACCCOMPANIED BY JOSEPH LEVITT, DEPUTY DIRECTOR FOR POLICY, CENTER FOR DEVICES IN RADIOLOGICAL HEALTH

Dr. KESSLER. Thank you, Mr. Chairman, very much.

The CHAIRMAN. Your full statement will be placed in the record, and we will ask you now to proceed.

Dr. KESSLER. Thank you, Mr. Chairman, again.

I am accompanied today by Mr. Joseph Levitt, who is the Deputy Director for Policy of our Center for Devices in Radiological Health.

Hearing impairment is a serious problem in this country. As we have already heard, an estimated 24 million people—nearly 1 in 10 Americans—suffer some degree of hearing loss.

A hearing aid that is properly fitted and properly used can improve life for many hearing impaired people, and you will hear today about the millions of Americans who are benefiting from this important medical device. But you will also hear that too many people who could benefit from hearing aids are either not purchasing them at all, or experiencing disappointment and frustration when they do.

Both statements are true, but the bottom line, I believe, is that the system can be and should be improved.

Today, I want to talk briefly about steps FDA is taking to do just that.

Our goal, Mr. Chairman, is quite simply, good care and realistic expectations for hearing impaired Americans.

Hearing aids are valuable medical devices. We must do what we can to see that those who could benefit from these devices, in fact, do.

First, let me address the issue of misleading advertising and promotion.

Earlier this year, FDA reviewed the advertising, promotional material, and labeling of hearing aids on the market today.

We found, unfortunately, that unsubstantiated performance claims were widespread—claims that created unrealistic expectations for their products, claims that were not backed by adequate scientific data.

For example, several companies claimed that their products would significantly improve speech recognition in noisy environments and simultaneously filter out background noise.

Certainly, significant technological advances have occurred over the past decade, but I have yet to see the hearing aid that can com-

pletely differentiate speech from unwanted extraneous noise. Yet that's just what some of the ads implied their product could do, and that's what consumers who bought them—most of them, who are elderly—expected them to do.

These inflated expectations account for some of the consumers' dissatisfaction—that witnesses at this hearing are describing today.

Based on our review, we sent letters to eight major hearing aid manufacturers directing them to immediately remove all misleading promotional material and advertising. We warned them that continued distribution of hearing aids with misleading claims could result in enforcement action, including seizure of the product.

We also advised the firms to correct the misconceptions they created by their misleading promotion and advertising, and I'm pleased to report today that all of the companies that we cited initially have removed the misleading claims identified in those warning letters.

Letters also have gone out to all other hearing aid manufacturers indicating that we believe that this is an industrywide problem, and directing them to review and correct their promotional literature and advertising as needed. We will continue to monitor those materials and take appropriate action.

Manufacturers who want to make a claim beyond the general statement of improved hearing, such as differentiating background noise from speech, will be required to submit supporting clinical trial data to FDA for review prior to making that claim. Consumers are entitled to truthful information about the benefits of a medical device.

Let me turn to a second area that FDA is addressing: hearing evaluations prior to the purchase of a hearing aid. This is a very important issue, and I can't emphasize it enough.

Hearing aids are not a one-size or one-variety-fits-all consumer product. Getting the right hearing aid is probably even more complicated than getting the right eyeglasses.

Consumers who are not properly evaluated, often purchase hearing aids that do not work or fit properly. They may even purchase two hearing aids when one would be sufficient, or buy one that is more costly than is required to address their individual hearing problem.

You will hear testimony today that makes it clear that many consumers are not receiving proper hearing evaluations—testimony indicating that expensive hearing aids are being laid to rest in dresser drawers because consumers didn't undergo proper hearing evaluation.

Hearing impaired Americans should not be out hundreds of dollars, only to have a hearing aid land in the dresser drawer.

Mr. Chairman, let me go back for a moment to the mid-1970's. Consumer groups, particularly the retired professional action group, as well as Congress and an HEW task force, all looked into the hearing aid system delivery in this country at that time.

One of the major problems they identified was that many consumers were not getting the proper diagnostic hearing evaluation prior to purchasing a hearing aid. Figures from the hearing aid industry indicated that about 40 percent of those buying hearing aids

were consulting solely with a hearing aid dealer before making the purchase.

This problem led the FDA to issue a regulation in 1977, restricting the sale of these devices to people who had undergone a hearing evaluation by a physician in the previous 6 months.

That regulation also included a provision allowing fully-informed adult patients to waive that medical evaluation. The waiver was expected to be used as the exception, but the evidence we now have, suggests that it is being used far more commonly.

For example, in 1991, an FDA survey of 11 hearing aid dispensers in Vermont found that 55 percent of the purchasers waived their medical evaluation, and in 20 percent of the cases, there were neither waivers nor physician statements in the patients' files.

Testimony you will hear today from the AARP about their survey of dispensers in Florida, and from the West Virginia Attorney General's Office, indicates that what we found in Vermont is also occurring elsewhere. The waivers are being overused and misrepresented.

This is a serious problem. Consumers are often unaware that it is critical to receive a comprehensive hearing evaluation prior to purchasing a hearing aid.

The hearing aid industry has become an increasingly aggressive, competitive business, and the current system makes it too easy for salespeople, eager to close the deal on the spot, to encourage consumers to sign the waiver and bypass the evaluation, and in some cases, as Mr. Darling will describe later, to provide inadequate testing in place of comprehensive evaluation that the consumers need.

We should be especially concerned about these, given that the majority of hearing aids are purchased by the elderly, and as the AARP notes in its report, studies show that elderly consumers are more trusting and less likely to recognize bad buying experiences.

Hearing aids can offer a real benefit, but the system today leaves too many consumers unable to reap that benefit. The system needs to be changed.

FDA will revisit the 1977 regulation with an eye toward revising them. We are looking at an approach that will say to the millions of hearing impaired Americans whose lives could be improved by using hearing aids, "You can be confident that when you go to purchase hearing aids, you will be properly informed, properly evaluated, and properly fitted by a competent, licensed health care professional." The States have an important—a crucial—role to play in this process.

FDA's concern is that the hearing test be conducted and interpreted competently. With input from health professionals, consumers, the industry, and our State colleagues, the agency is considering setting up minimum criteria for the comprehensive hearing evaluations, and is examining whether any circumstances warrant a waiver.

We believe that the steps we are taking will help more Americans take advantage of these very, very important devices. Thank you very much.

[The prepared statement of Dr. Kessler follows:]



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

STATEMENT BY
DAVID A. KESSLER, M.D.
COMMISSIONER
FOOD AND DRUG ADMINISTRATION
PUBLIC HEALTH SERVICE
DEPARTMENT OF HEALTH AND HUMAN SERVICES

Thank you Mr. Chairman, and members of the Committee: I am pleased to appear before you today to discuss this important health matter.

Hearing impairment is a serious problem in this country. An estimated 24 million people--nearly one in ten Americans--suffer some degree of hearing loss.

A hearing aid that is properly fitted and properly used can improve life for many hearing-impaired people. And you will hear today about the millions of Americans who are benefiting from these important medical devices. But you will also hear that too many people who could benefit from hearing aids are either not purchasing them at all or are experiencing disappointment and frustration when they do.

Both statements are true. But the bottom line is that we believe the system can be improved.

Today, I want to talk briefly about steps FDA is taking to do that. Our goal, Mr. Chairman, is quite simply good care and realistic expectations for hearing-impaired Americans. Hearing aids are valuable medical devices. We must do what we can to see that those who could benefit from these devices in fact do.

First, let me address the issue of advertising and promotion. Earlier this year, FDA reviewed the advertising, promotional

material, and labelling of hearing aids on the market today. We found that unsubstantiated performance claims were widespread. Claims that created unrealistic expectations for their products. Claims that were not backed by adequate scientific data.

For example, several companies claimed that their products would significantly improve speech recognition in noisy environments, and simultaneously filter out background noise. Certainly significant technological advances have occurred over the past decade, but I have yet to see the hearing aid that can completely differentiate speech from unwanted extraneous noise.

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Consumers are entitled to truthful information about the benefits of a medical device.

Let me turn to a second area that FDA is addressing: hearing evaluations prior to purchase of a hearing aid.

This is a very important issue. I can't emphasize it enough.

Hearing aids are not a "one size or one variety fits all" consumer product. Getting the right hearing aid is probably even more complicated than getting the right eyeglass prescription. There is no way that a consumer can confidently select the appropriate hearing aid without undergoing a proper hearing evaluation.

Consumers who are not properly evaluated often purchase hearing aids that do not work or fit properly. They may even purchase two hearings aids when one would be sufficient, or buy one that is more costly than is required to address their hearing problem.

But you will hear testimony today that makes clear that many consumers are not receiving the proper hearing evaluation. Testimony indicating that expensive hearing aids are being laid to rest in dresser drawers because consumers didn't undergo the proper hearing evaluation. Hearing-impaired Americans should not be out hundreds of dollars only to have a hearing aid land in the dresser drawer.

Mr. Chairman, let me go back for a moment to the mid-1970s. Consumer groups, particularly the Retired Professional Action Group, as well as Congress and an HEW task force, all looked into the hearing aid delivery system in this country.

One of the major problems they identified was that many consumers were not getting the proper diagnostic hearing evaluation prior to purchasing a hearing aid. Figures from the hearing aid industry indicated that about 40 percent of those buying hearing aids were consulting solely with a hearing aid dealer before making the purchase.

This problem led FDA to issue a regulation in 1977 restricting the sale of these devices to people who had undergone a hearing evaluation by a physician in the previous six months. But that regulation also included a provision allowing fully informed adult patients to waive the medical examination.

The waiver was expected to be used as the exception, but the evidence we now have suggests that it is being used far more commonly. For example, a 1991 FDA survey of 11 hearing aid dispensers in Vermont found that 55% of the purchasers waived the medical evaluation, and in 20% of the cases there were neither waivers nor physician statements in the patient files.

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The waivers are being overused and misrepresented.

This is a serious problem. Consumers are often unaware that it is critical to receive a comprehensive hearing evaluation prior to purchasing a hearing aid. The hearing aid industry has become an increasingly aggressive, competitive business. And the current system makes it too easy for salespeople eager to close the deal on the spot to encourage consumers to sign the waiver and bypass the evaluation: in some cases--as Mr. Darling will describe later--to provide inadequate tests in place of the comprehensive evaluation consumers need.

We should be especially concerned about this given that the majority of hearing aids are purchased by the elderly. As the AARP notes in its report, studies show that elderly consumers are more trusting and less likely to recognize bad buying experiences.

Hearing aids can offer a real benefit, but the system today leaves too many consumers unable to reap that benefit. The system needs to be changed. FDA is now revisiting the 1977 regulations with an eye toward revising them.

We are looking at an approach which will say to the millions of hearing-impaired Americans whose lives could be improved by using hearing aids: you can be confident that when you go to purchase hearing aids, you will be properly informed, properly evaluated, properly fitted by a competent, licensed health care professional.

The states have an important role to play in this process. FDA's concern is that the hearing tests be conducted and interpreted competently. With input from health professionals, consumers and industry, the Agency is considering setting out minimum criteria for the comprehensive hearing evaluations, and whether there are any circumstances that would warrant a waiver.

We believe that the steps we are taking will help more Americans take advantage of these important medical devices.

Thank you. That concludes my testimony. My colleagues and I will be glad to answer any questions you have.

Senator COHEN [assuming Chair]. Thank you very much, Dr. Kessler, for that impassioned testimony. I'd like to refer back to the survey that was conducted by the FDA's New England field office in Vermont.

You indicated that the survey included the examination of some 611 hearing aid sales records from about 11 hearing aid dealers, and as I recall, you said that in 55 percent of the cases they waived the requirement for a physician's examination—

Dr. KESSLER. That's right.

Senator COHEN. Or the request for it. And in 20 percent—what was the other figure you quoted? 20 percent?

Dr. KESSLER. Twenty percent, that's correct.

Senator COHEN. Twenty percent—what?

Dr. KESSLER. They didn't have any evidence of the examination or the waiver in the files.

Senator COHEN. All right. Now let me just ask, hypothetically, does the mere fact that there are 55 percent of the cases waived, in those that were examined, mean that those individuals who were fitted received inappropriate care or nonfunctioning or malfunctioning devices?

Dr. KESSLER. We don't know—can't answer that.

Senator COHEN. We have a situation as Senator Kohl touched upon it, that suppose you live in the far reaches of Maine or Wisconsin or Arkansas and you may not have an ear, nose, and throat physician available. Maybe you'll have a general practitioner, but there's no guarantee that a general practitioner has the expertise in the field of examining the ear with the kind of specialty that's required. Does that mean that in those areas where they don't have these experts available, that we should insist upon a mandatory physician's examination?

Dr. KESSLER. I believe today with the technology available in hearing aids, that to benefit from a hearing aid, you need to be evaluated properly. I don't think you can benefit from a hearing aid if you're not evaluated properly.

I think that requires a comprehensive hearing evaluation. I think it—you just need to be assessed. What it requires is that the test be administered and interpreted properly.

That's not just simply that you're able to be fitted for the hearing aid, it's that you have a comprehensive hearing evaluation.

I believe, as a physician, that people beyond those who hold an M.D. degree are certainly competent to do comprehensive hearing evaluations. What I'm concerned about is that people are going in and buying hearing aids and not receiving that comprehensive hearing evaluation.

I think that the requirement that we set up in 1977—it had two problems. The first problem was that you had to have an M.D., and the second problem was that you could waive.

I think it's worth re-looking at that entire framework. I think we need a framework that focuses more on what a comprehensive hearing evaluation is, and then allow our State colleagues to license people who are competent to do that comprehensive hearing evaluation. At least to me, personally, it makes a lot more sense.

Senator COHEN. Does that require then an M.D.—a physician or general practitioner—to conduct the examination at a bare minimum? Is that what you're saying?

Dr. KESSLER. No.

Senator COHEN. That it be a trained—

Dr. KESSLER. I think there are people beyond M.D.s—

Senator COHEN. They'd be below M.D.'s, I'm asking you.

Dr. KESSLER. I'm sorry?

Senator COHEN. Does it have to be beyond M.D.s or below M.D.s? In other words, can you have less than a general physician's degree and still qualify as an expert in the field of examining a person for a hearing aid, or does that individual have to have something greater than an M.D.'s training?

Dr. KESSLER. Let me just talk from this M.D.'s experience—let me use mine. I, and I consider myself a, you know, relatively well-trained physician, I am not an ENT, an otolaryngologist, I'm a pediatrician. I am not competent—I have never been trained to do a comprehensive hearing evaluation.

I mean, I would certainly much rather—I think many audiologists, for example, are much more trained than I would ever be trained to do these tests, and I would certainly think that there are many people who don't hold an M.D. degree—certainly audiologists—I mean, who have demonstrated exquisite competence to administer this kind of comprehensive hearing evaluation. And it's possible that there are people who are not even audiologists.

I think we have to focus on what tests need to be done, and then require competence in those tests.

I think the notion that you just have to be an M.D. or waive—I don't think that gets at the heart of the issue.

Senator COHEN. Well, is it fair to say that one of the reasons why it's recommended that you normally would consult a physician is that that physician would at least conduct an examination to find out whether you have, let's say, a tumor in the ear canal that might be accounting for the impairment, and that that physician would at least recognize or conduct tests that would determine that there's no underlying cause that needs to be treated from a physician's point of view?

That's number one.

Number two, that a physician, if he is like you, would recognize that he or she is not a specialist that is trained in the field and would recommend and refer that patient to an audiologist or to someone who has greater specialty? That this provides the maximum kind of protection to the consumer? Is that what—

Dr. KESSLER. No. I think, Senator, that a comprehensive hearing evaluation should be the first step—

Senator COHEN. What does that entail? What are we saying?

Dr. KESSLER. I think that—again, we are analyzing it right now to decide what exactly goes in—what makes up a core—

Senator COHEN. What is a comprehensive analysis?

Dr. KESSLER. Well, I think you certainly—the things that we're considering in a comprehensive hearing assessment—I mean, it could include, you know, air and bone conduction tests, pure audiometry, speech audiometry, even site of lesion testing. And that

kind of testing could be very competently, in my opinion, performed by an audiologist—that's the first step.

And not only performed, but assessed. If you assess the results of those tests, you will know whether there is reason or there is a possibility that there is a medical or surgical cause. This may not be a straightforward hearing loss.

Then I believe if you have that comprehensive hearing evaluation, and that's done by someone who's trained to assess the results, and there's reason to suspect that there may be a medical or surgical lesion or problem, then the person can be referred to somebody to rule out a tumor.

I don't think the first thing you do is go rule out the tumor.

Senator COHEN. We understand that the Federal Trade Commission is now investigating possible violations by two manufacturers who had previously signed consent orders regarding misleading advertising. What is the level of coordination between the FDA and FTC?

Dr. KESSLER. Very strong. I mean, we are working very closely with each other.

Since we have begun our investigations, we have met almost on a constant basis to coordinate those efforts.

Senator COHEN. My understanding is that the States of Kansas, Idaho, Missouri, Florida, and Washington have been leading campaigns to either restrict or completely ban mail-order hearing aid sales within their borders, and that even the Direct Marketing Association, which is a nonprofit membership organization of mail order companies, has stated in a hearing trade publication that a consumer with a hearing problem should purchase an aid only under the direction of a licensed physician or professional.

What would you recommend in the way of Federal regulations covering the sale of hearing aids by mail?

Dr. KESSLER. I can't figure out how you get evaluated by mail.

What I'm saying today is that I think everyone who buys a hearing aid should be evaluated by someone who's competent, and I don't know how that happens by mail.

Senator COHEN. Are you going to recommend that there be a Federal regulation banning the sale of hearing aids by mail?

Dr. KESSLER. I think that's something that we need to work on with this Committee and we need to look at.

Senator COHEN. Senator Kohl.

Senator KOHL. Well, thank you very much, Senator Cohen.

I just want to read again to you what I believe we have operative in Wisconsin, Dr. Kessler.

In Wisconsin, we have strict licensing, testing, and professional competency standards for all hearing professionals, including hearing instrument dispensers, audiologists, and speech pathologists.

As you know, these are highly trained people who are capable of conducting thorough hearing examinations.

In Wisconsin, in the rare cases of abuse, we do have a professional review board which also has citizen members that can and does take the disciplinary action and revoke licenses.

Is this the kind of operation that you would like to see replicated in all 50 States?

Dr. KESSLER. I certainly would strongly suggest that kind of scheme—that framework—be replicated. I think licensure to insure competence is absolutely critical and needs to apply in all 50 States—yes.

Senator KOHL. So what you would like, as we understand—what you may very well decide to do is require that before purchasing a hearing aid, all people would be required to have some sort of examination, not necessarily conducted by a physician, but by a qualified, trained professional.

Dr. KESSLER. Absolutely, Senator.

Senator KOHL. As a direction in which you believe you're going.

Dr. KESSLER. That's correct, Senator.

Senator KOHL. Finally, as you know, currently, Medicare does not cover most hearing exams. If, in fact, we're going to go in the direction in which you are suggesting, do we need to have that hearing exam covered by some sort of insurance?

Dr. KESSLER. I think that the—obviously, you first have to look at it with respect to whether you're covering devices, and I certainly yield to the President—I mean, next week, he's certainly not going to get into these kinds of specifics, but if one's talking about paying \$1,000—or we heard \$2,000 this morning—I think we can't be—if, in fact, \$50 is going to make the difference between whether a \$1,000 investment is going to be worth making, it certainly seems to me that it's an investment that is worthwhile.

Can I just back up for a second to your previous point?

I am all in favor of licensure. I think that's the answer. I think that the issue, though, is what we are licensing.

I think that even though States have licensure—I think that licensure in some States is dependent solely on good moral character and not having contagious diseases. That's not the kind of licensure that I'm talking about.

I'm not talking about simply the licensure that allows one to fit a hearing aid. I am talking about licensure that says, "This person that we're licensing is competent to perform a comprehensive hearing evaluation and assess the results"—and assess the results in such a way that if there is an underlying medical reason, that person is trained by experience to be able to refer that patient to a physician to rule out an important medical or surgical condition.

Senator KOHL. Well, you're absolutely right. I'll call just to your attention something that I'm sure you know—that in the State of Wisconsin, that licensure you're talking about is only granted after an examination that covers the things that you would suggest are necessary in order to license somebody beyond their character—that they have to have the kinds of experience, background, and qualifications to truly be able to conduct a good hearing examination, which is, I think, what you're referring to.

Dr. KESSLER. That's the direction we're moving in, and I certainly applaud those States—I mean, that have already taken that initiative, and we want to work with them. What our goal is, is to bring all States and to work with all States so that every citizen in this country can benefit such as the citizens in your State.

Senator KOHL. Thank you, Dr. Kessler.

Thank you, Senator Cohen.

Senator COHEN. Dr. Kessler, would you comment about Vermont's request for an exemption from the waiver requirement? You didn't refer to this in your testimony.

My understanding is that Vermont has passed legislation which is more restrictive than the current Federal law requires. You can, for example, have a waiver of a physician's exam, and Vermont has said, "No option to waive that." Because of their strict law, Vermont has requested an exemption from the FDA.

I was wondering, if they have more stringent laws, what has been the delay in granting Vermont an exemption?

Dr. KESSLER. We've held public hearings on the Vermont waiver, and I have even looked at it myself. We certainly are sympathetic with Vermont's concern; the waiver system—I mean, is not working.

Let me say today, Senator, that we would be inclined to grant Vermont's waiver, and I will write to Vermont shortly and say that we are inclined to grant Vermont's waiver, if there are certain changes made in their waiver.

I think that eliminating the waiver, when they have evidence that the waivers are being abused, I think, makes a lot of sense for the State to do. The concern I have is limiting the review of this comprehensive hearing evaluation only to physicians.

I think that if the State were willing to broaden that to licensed health care professionals who met certain competency tests, then we would be inclined to grant their request for exemption to allow the elimination of waivers and allow the evaluations to be performed by licensed health professionals. But we don't believe that it's only if a physician who—we'd ask them to broaden their consideration of who's competent to administer those hearing evaluations.

Senator COHEN. Has FDA done this yet? Have you advised Vermont that you would be willing to grant that exemption, provided certain changes were made?

Dr. KESSLER. We've been in some discussions, but as I said, Senator, we would be inclined to do that, and I expect to be writing to Vermont later this week or next week indicating exactly what I've said to you.

Senator COHEN. Okay. One of the frustrations on the part of all of our constituents is to get responses and action out of the Federal bureaucracy.

This request has been pending since July 21, 1989, so I think it's time to communicate what needs to be done, so it can be done, and not leave it pending for 3 or 4 years.

Dr. KESSLER. I am in full agreement with that.

Senator COHEN. Thank you very much. We appreciate your testimony. It's been very important to the hearing.

Dr. KESSLER. Thank you.

Senator COHEN. Thank you for all of your help to our Committee staff in sharing the kinds of complaints that your office has been investigating.

Dr. KESSLER. Senator, just one last point—you should just know, we are in complete agreement with the findings of your investigation staff—of this Committee—and certainly, the report that you will hear from AARP, I think, is an extraordinary attempt to put this whole issue into perspective.

Senator COHEN. Thank you.

Our next witnesses will be Mr. Don Darling, who is the Deputy Attorney General for the State of West Virginia, and Dr. Mildred Dixon of Clinton, Maryland, the Vice President of the American Association of Retired Persons. In this capacity, she serves on the Board of Trustees for AARP's Financial Investment Plan, and on the Board of Counselors of the Andress Gerontology Center at USC.

We also have Donna Sorkin, the Executive Director of Self Help for the Hard of Hearing, the Nation's largest consumer organization for hard of hearing people. She brings a uniquely personal insight into an experience with hearing loss and its impact.

Welcome, all of you, and Dr. Dixon, would you like to proceed first?

STATEMENT OF DR. MARGARET DIXON, VICE PRESIDENT, AMERICAN ASSOCIATION OF RETIRED PERSONS

Dr. DIXON. Thank you, Senator Cohen.

I am Margaret Dixon, Vice President of the American Association of Retired Persons.

Senator COHEN. We have "Mildred" in front of your name tag, so we'll correct that.

Dr. DIXON. Yes. I was looking for my name.

AARP very much appreciates this opportunity to testify on hearing aid sales and the regulation of the market. As part of our statement to the Committee, AARP is releasing today a study entitled, "A Report on Hearing Aids: User Perspectives and Concerns."¹

AARP encourages its members to have their hearing evaluated, and when appropriate, to be fitted with a hearing aid. Neither our testimony today nor our report should be construed as a reason for anyone to put off a hearing evaluation and to buy an aid if one is needed.

Hearing aids, with sales of 1.8 million units a year, represent a \$1 billion-plus industry. People over 65 constitute the largest segment of the population with a hearing loss and are the principal purchasers of hearing aids.

Hearing instruments are quite expensive, with many devices costing more than \$600. In addition, about half of all users wear two aids. Such purchases are not reimbursed under Medicare or by most other third-party payers, so they represent significant out-of-pocket expenditures.

Given this, hearing aid sales practices are of particular importance to low, moderate, and fixed income consumers.

AARP's research consists of two separate components:

First, a shopping experience study where consumer testers were evaluated for hearing aids in two cities in Florida.

Second, an analysis of 4,000 letters sent by AARP members—hearing aid device users—in response to an article in our newspaper, "The Bulletin."

AARP commissioned a shopping experience study using volunteer consumer testers. We wanted to know if competent practitioners

¹ See Appendix 1.

are following accepted standards of practice in hearing aid evaluations and sales.

Sixteen teams of two testers each visited 23 different hearing aid sales operations in these two cities. We heard earlier from Ms. Lomax, who was one of these volunteers.

There were a total of 169 hearing evaluations that took them 10 to 105 minutes. The principal finding of this research was, that while many hearing aid sellers met or exceeded State testing standards, many did not. Moreover, the quality of these examinations and the conclusions drawn varied extensively.

Overall, evaluators recommended hearing aids to 57 percent of the consumer testers. However, the differences among sellers with the same pool of consumer testers were startling.

In one Tampa site, 33 percent of the consumer testers received the recommendation that they needed an aid. In another site, 80 percent of those same testers were recommended an aid.

In West Palm Beach, a second group of testers found that the range among sites went from 50 percent to 90 percent.

Obviously, when the range of recommendations varies from 40-50 percentage points, something is wrong.

At 11 sites, consumer testers reported that their hearing was evaluated in noisy rooms.

In addition, participants reported a series of statements made by different sellers that appeared to be unfair and deceptive. These include statements that it was in the consumers' interest not to see a physician before purchasing an aid, or a hearing aid would exercise the nerve and slow down the hearing loss, or that a hearing test was unnecessary because the hearing aid he recommended used 24 karat gold circuits.

The second component of the report is based on consumers' feedback about their hearing aids.

In September 1991, the AARP "Bulletin" published a small article directed toward hearing aid users. Readers were asked to share their experiences about their hearing aids.

Most of the letter-writers were older—over age 70—long-time, full-time users—67 percent wear their hearing aids all day long.

The most significant finding was that these users expressed a relatively low level of satisfaction with their aids. Only 43 percent of the letter-writers made positive comments about their aids, and 34 percent made negative comments.

Because of the nature of hearing aid purchases, the vulnerability of older consumers, and the troublesome sales practices associated with this industry, there is a continuing need for proactive oversight at both the Federal and State levels. Indeed, the potential for improving consumer protections for older users has never been greater.

Bringing this about will require concerted efforts by both Federal and State agencies.

To this end, AARP recommends that Federal and State regulators heighten enforcement and regulatory activities in policing the marketplace to insure competency, integrity, fairness, and accuracy.

Second, that national standards of practice for all hearing evaluations be established, that consumers be educated on what to ex-

pect of a hearing evaluation, that the FDA adopt minimum levels of competency for all practitioners, that States be allowed to adopt stronger standards if they see fit, that the FDA or the State should require a 30-day return period for the sale of all hearing aids, particularly for first-time buyers, and that the FDA continue its course of requiring clinical data to substantiate manufacturers' claims.

In conclusion, AARP commends the Committee, especially Senator Pryor and Senator Cohen, for your aggressive efforts to call attention to this issue. We believe that increased Federal and State action in this area can make an important difference in the lives of millions of older Americans. Thank you.

[The prepared statement of Dr. Dixon follows:]



Bringing lifetimes of experience and leadership to serve all generations.

STATEMENT OF THE
AMERICAN ASSOCIATION OF RETIRED PERSONS
ON
HEARING AIDS AND OLDER CONSUMERS

The American Association of Retired Persons (AARP) appreciates this opportunity to testify on hearing aid sales and the regulation of this market. As part of our statement to the committee, AARP is releasing today a study entitled, A Report on Hearing Aids, User Perspectives and Concerns. It summarizes more than 18 months of consumer research and forms the basis for many of our comments. This document is one in a series of reports AARP has produced which looks at consumer goods and services marketed to older adults.

AARP encourages its members to have their hearing evaluated and, when appropriate, to be fitted with a hearing aid(s). There are an estimated 23.5 million people in our nation with a hearing loss. Over half (60 percent) of these are 65 or older. However, only 3.78 million people wear hearing aids. That means there are between 15 and 20 million people who could benefit from wearing these devices and do not. Without an aid, many older Americans find themselves cut out of even the most basic communications of everyday living. Hearing aids can make a difference. In one study, 65 percent of hearing aid users indicated these devices improved their lives.

Our research indicates that consumers face serious problems in the hearing aid marketplace. With stepped-up oversight by the Congress, the regulatory reforms proposed by the FDA, proactive enforcement by federal and state regulators, and self-regulation by the industry, we hope these problems will be corrected. However, neither our testimony nor our report should be construed as a reason for anyone to put off a hearing evaluation and to buy an aid if one is needed. Instead, we encourage consumers to protect themselves by reviewing some of the buying tips listed at the end of our testimony.

AARP REPORT

One of our Association's objectives is to seek a fair marketplace for all older Americans. That is why we conducted the research and published the report on hearing aids. We wanted to identify consumer problems, increase awareness about the marketplace, and provide consumers with helpful information about market conditions.

Hearing aids, with sales of 1.8 million units a year, represent a billion dollar plus industry. People over 65 are both the principal purchasers of hearing aids (65 percent) and the largest segment of the population with a hearing loss. Sales practices associated with hearing aids are of tremendous importance to many older Americans. Hearing instruments are quite expensive. Many devices cost more than \$600. What's more, about half of all users wear two aids. Since such purchases are not reimbursed under Medicare or by most other third-party payers, they represent significant out-of-pocket expenditures. Given this, hearing aid sales practices are of particular importance to low-, moderate-, and fixed-income consumers.

AARP's research consisted of two separate components:

- A shopping experience study where consumer testers were evaluated for hearing aids in two cities in Florida.
- An analysis of 4,000 letters sent by AARP members/hearing aid device users in response to an article in our newspaper, the Bulletin.

Let me summarize some of the key elements of each of these items. For more detailed information, I refer you to the report itself.

SHOPPING EXPERIENCE STUDY

Purchasing an aid(s) can be a confusing process, particularly for first-time buyers.

The list of manufacturers, practitioners, and regulators can be baffling. While the same kinds of electronic chips may be used in manufacturing a hearing aid as in consumer electronics, buying an aid is not like purchasing a color TV or VCR. As with most medical devices, the buyer must rely on the seller to evaluate need and recommend a product to match the hearing loss.

AARP commissioned a shopping experience study using volunteer consumer testers to document how this process worked. We wanted to know if competent practitioners are following accepted standards of practice in hearing aid evaluations and sales. Second, we wanted to know the level of regulatory compliance. Florida was selected because of its large population of elders, significant hearing aid sales, and strong regulatory standards.

Sixteen teams of two testers each (six teams in Tampa and ten teams in West Palm Beach) visited 23 different hearing aid sales operations in these two cities. There were a total of 169 hearing evaluations that took from 10 to 105 minutes. After each visit, team members recorded what happened on special forms. These reports were coded and analyzed by researchers from the Institute for Technology Development (ITD).¹

¹ITD is a private research institute that conducts research into, among other things, goods and services marketed to older persons. Dr. Margaret Wylde, an ITD Vice-President who is also a Ph.D. audiologist, conducted this research for AARP.

The principal finding of this research was that while many hearing aid sellers met or exceeded state testing standards, a significant number did not. Moreover, the quality of these examinations and the conclusions drawn varied extensively. For example, Florida regulations require an otoscopic examination of both ears. Three practitioners failed to conduct these examinations with a number of testers.

State and federal regulations required a pure tone air and pure tone bone examination with each subject (see pages 56-59 of the report for definitions and details). However, consumer testers reported that in 41 percent of the cases, an aid was recommended without conducting one of these two most basic tests. Pure tone air and bone tests are used, in part, to determine if there is a medically treatable condition.

Overall, evaluators recommended hearing aids to 57 percent of the consumer testers. However, the differences among sellers with the same pool of consumer testers was startling. In one Tampa site, 33 percent of the consumer testers received a recommendation that they needed an aid. In another site, 80 percent of those same testers were recommended an aid. In West Palm Beach, a second group of testers found that the range among sites went from 50 percent to 90 percent. Obviously, when the range of recommendations varies from 40 to 50 percentage points, something is awry. Serious questions are raised about adherence to standards² and good practice.

At 11 sites, consumer testers reported their hearing was evaluated in "noisy rooms." They reported hearing traffic, the hum of an air conditioner, people talking in the next room, a gardener working outside, and other noises while their hearing was

²By contrast, the ITD audiologist, who trained and evaluated each consumer testers' hearing before this study began, would have recommended an aid for 45 percent of these individuals.

evaluated. Florida has standards for limiting background noise during audiometric testing to insure proper hearing aid evaluations. Being tested in a "noisy" room would not meet these standards.

Finally, consumer testers reported a series of statements and practices made by different sellers that appear to be unfair and deceptive. These include the following:

- In a number of cases, sellers recommended aids to consumers who were clearly not candidates for such devices.
- One stated it was in the consumer's interest *not* to see a physician before purchasing an aid.
- One stated a hearing aid would "exercise the nerve and slow down the hearing loss."³
- One stated a 30-day trial period would be unnecessary since the aid he recommended used 24K gold circuits.
- One stated a hearing aid was needed right away and coupled this with a refusal to provide price information until a sale was consummated.
- In the Tampa sites, 75 percent of the sellers had a sign stating itemized prices were available. In West Palm Beach, only 67 percent posted such a sign.⁴

After the shopping test was completed, we asked testers what they would recommend to first-time buyers. They offered two strong suggestions: (1) buyer beware and (2) shop around.

While Florida's hearing aid regulations are some of the strongest in the country, apparently they are no guarantee of adequate consumer protection. They do not appear

³Florida regulations prohibit statements that a hearing aid will retard the progression of a hearing impairment.

⁴Florida requires the posting of a sign stating itemized prices are available in every location.

to ensure that the hearing evaluation and recommendation consumers receive is either complete or accurate. Florida does not have a proactive system of auditing sellers to determine compliance with its standards. Instead, the state Department of Business and Professional Regulation, like many other states, relies upon complaints to trigger an investigation. In comments on an earlier draft of this report, the chief of the department's Bureau of Investigative and Consumer Services wrote that the report "provides significant justification for proactive regulation."

CONSUMER RESPONSE

The second component of the report is based on consumers' feedback about their hearing aids. In September of 1991, the AARP Bulletin published a small article directed toward hearing aid users. Readers were asked to share their experiences about their hearing aids (see the appendix in the report). The first 4,000 letters received were tabulated and analyzed (a total of 8,000 responses were ultimately mailed).

Most of the letter writers were older (over age 70), long-time, full-time users -- 67 percent wear their aids all day long. The most significant finding was that these users expressed a relatively low level of satisfaction with their aids. Only 43 percent of the letter writers made positive comments about their aid and 34 percent made negative comments⁵.

An analysis relating positive and negative AARP letters to brands purchased was also conducted. It found that the percentage of positive letters varied from 32 percent to

⁵The letters received by AARP (see report for details) represent one of the largest collections of user opinion on hearing aids collected to date. However, letter writers self-selected themselves. Therefore, the results cannot be generalized to all hearing aid users or to the older population.

55 percent according to the particular brand. Negative letters ranged from 19 percent to 55 percent.

REGULATORY ACTIVITY

Consumer satisfaction and dissatisfaction are important elements of marketing strategies. They also serve as catalysts for implementing or blocking consumer protections.

The FTC, Food and Drug Administration (FDA), state licensing boards, and attorneys general all have overlapping authority over the hearing aid marketplace. Since 1985, however, there has been little activity in this important area even though consumer satisfaction is relatively low.

The FTC has a long history of regulatory action relating to hearing aids. Between 1934 and 1976, this agency obtained orders, consent decrees, or voluntary compliance actions in 66 different cases. Because of this level of activity, commission staff had sought a trade rule in 1975 to impose comprehensive requirements on sellers and manufacturers. However, this rulemaking proceeding was dropped in 1985 on the basis of an FTC study (Market Facts, 1984) showing an 84% satisfaction level among hearing aid purchasers. Notably, recent industry studies (MarketTrack I, II, and III, 1989-91) have found much lower levels of consumer satisfaction -- ranging between 55 and 58 percent.

Since that rulemaking proceeding was terminated, the FTC has reported taking two enforcement actions. Both involved dispensers. Based on a Dahlberg Inc. news release (Dahlberg manufactures Miracle-Ear), the FTC appears to be currently reviewing

advertising claims by this firm. This review is based on a 1976 consent decree with the FTC signed by Dahlberg.

The FDA has nominally regulated hearing aids as medical devices since 1977, primarily in the areas of safety and efficacy of these devices. FDA focused only minimal attention on hearing aids until this year.

The most specific regulations are based at the state level. Hearing specialist and audiology boards can establish standards of practice and set competency standards for practitioners. According to a recent consumer survey of hearing specialist boards⁶, "most boards have adequate oversight, disciplinary, and enforcement powers, but seldom use them" (*emphasis added*). For a three year period, 10 boards took no action and 12 others were only minimally active.

AARP applauds recent actions by the FDA to correct what it called "misleading claims" and the commissioner's call to reform the agency's hearing aid regulations. Recent FTC actions also demonstrate renewed interest in this area. AARP looks forward to working with the FDA, FTC, and designated state agencies in addressing advertising and sales problems relating to hearing aids. Clearly, remedial action is needed at both federal and state levels.

Because of the nature of hearing aid purchases, the vulnerability of older consumers, and the troublesome sales practices associated with this industry, there is a continuing need for proactive oversight at both the federal and state levels. Indeed, the

⁶Lewis, E.J., P.R. Powers, et.al., Protecting The Hearing Aid User: State Regulation Of Hearing Aid Dispensers.

potential for improving consumer protections for older users has never been greater.

Bringing this about will require concerted efforts by both federal and state agencies.

AARP recommends that:

- Federal and state regulators heighten enforcement and regulatory activities in policing the marketplace to ensure competency, integrity, fairness, and accuracy. Relying merely on complaints does not gauge the true extent of consumer problems. Much more needs to be done to monitor complaints.
- National standards of practice for all hearing evaluations need to be established. Attendant consumer education would educate consumers on what to expect in a hearing evaluation.
- The FDA should adopt minimum levels of competency for all practitioners. States should be allowed to adopt stronger standards as they see fit.
- The FDA and/or the states should require a 30-day return period for the sale of all hearing aids, particularly for first-time buyers. Manufacturers offer dispensers 60- to 90-day return periods for credit. Consumers need a similar grace period. In many ways, if properly used, a trial period is the consumer's most important protection. This protection is already on the books in more than ten states.
- The FDA should continue its course of requiring clinical data to substantiate manufacturers' claims. Misleading, false, or deceptive advertising should be prohibited and aggressively policed. Because of the nature of this product, the standard of proof may not need to meet the criteria of double-blind studies.

When shopping for a hearing aid, AARP recommends consumers become careful shoppers. Shopping tips which should assist buyers include the following:

- 1) Be an educated consumer. Go to the library and learn about hearing aids and hearing evaluations prior to making a purchase. There are a number of excellent resources

available for first-time buyers.⁷ Learn about service providers and the range of services and products they offer. Check your telephone's Yellow Pages for practitioners in your area.

- 2) If you're a first-time buyer, be sure to visit a physician, preferably a specialist in treating hearing impairments, for a medical examination before buying an aid.
- 3) Try to have your hearing evaluated by a certified audiologist. Audiologists generally are the most knowledgeable of the practitioners that evaluate and fit hearing aids. They also conduct the most thorough evaluations.
- 4) Be on your guard. There are practitioners in all occupations who are more interested in a sale than your welfare.
- 5) Secure a written quotation for the hearing test, hearing aid and all other associated costs. Costs do vary but shouldn't be the only consideration in buying an aid.
- 6) Secure a copy of your audiogram in addition to any other hearing test results. If you don't understand test results, ask more questions.
- 7) Be skeptical about any claims made for the product and any high pressure tactics.
- 8) Demand a 30- to 60-day trial period to test the aid in your hearing environment. The cost to you if you return the aid, should be minimal. Be sure to ask how the trial period works.
- 9) Practice with the aid during your trial period and attend all scheduled follow-up sessions.
- 10) Accept the fact that even the best aid, fitted by the most competent individual, may need to be remade or adjusted. It is also the consumer's responsibility to work with the seller.
- 11) If you're not satisfied, return the aid within the trial period.
- 12) If necessary, file a complaint with the state licensing board, your attorney general, and the Federal Trade Commission or the Food and Drug Administration.

⁷Consumers can also get a free copy of AARP's guide to hearing aids by writing: Product Report: Hearing Aids (D13766), AARP (EE0458), PO Box 22796, Long Beach, CA 90801-5796 (Please allow four to six weeks for delivery.)

NOTE.—Subsequent to the hearing Senator Simpson submitted questions for Dr. Dixon. They are listed in Appendix 2.

Senator COHEN. Thank you very much, Dr. Dixon.

Mr. Darling.

STATEMENT OF DON DARLING, DEPUTY ATTORNEY GENERAL, STATE OF WEST VIRGINIA

Mr. DARLING. Thank you, Senator Pryor and Senator Cohen. My comments today are from the perspective of someone who is charged with enforcing consumer protection laws.

Hearing loss is an affliction that affects approximately 24 million people in the United States, the majority of which are elderly.

Elderly individuals who suffer from hearing loss and refuse to purchase a hearing aid commonly withdraw from society because of their inability to socialize and communicate with others, and because of society's intolerance toward their affliction.

Conversely, elderly consumers that decide to purchase hearing aids to compensate for their hearing loss are faced with a daunting and confusing task of choosing from whom to purchase a hearing aid.

The skill and competency of hearing aid dispensers varies greatly in degree. As a result, elderly consumers purchasing hearing aids are frequently sold hearing aids that are not suited to their needs because of inadequate testing and fitting by incompetent and fraudulent dispensers.

The West Virginia Attorney General's Office has long been a firm advocate of protecting the rights of the elderly in consumer matters.

West Virginia opened its first wide-scale investigation of hearing aid dispensers in 1992 at the request of elderly consumers and the West Virginia Board of Hearing Aid Dealers.

The investigation focused on a Charleston, West Virginia-based "Miracle-Ear" franchise dealer doing business as "Miracle-Ear Hearing Aid Center."

During the course of the investigation, thousands of documents were reviewed and analyzed by clinical audiologists and medical doctors, and formal and informal testimony of numerous experts was consulted.

After review and examination of audiograms, the medical experts uniformly concluded that the documents reflected incompetent testing and a lack of reliability or validity of the test as a whole, resulting in sales of unnecessary or inadequate hearing aids.

The investigation of the "Miracle-Ear" franchise also included interviews with elderly consumers filing complaints with the Consumer Protection Division of the Attorney General's Office.

In virtually every interview conducted, the consumer stated, "I could hear better without the hearing aid than with the hearing aid," and "I have kept the hearing aid in my dresser drawer because the aid was not benefiting my hearing."

The majority of the consumers interviewed expressed dissatisfaction with the level of performance. The consumers' dissatisfaction seemed to stem primarily from inflated expectations consumers had from deceptive advertisements by the hearing aid manufacturers.

Interviews with elderly hearing aid purchasers also led to the discovery that many elderly consumers were assessed excessive finance charges without their knowledge.

Elderly consumers, unable to pay the cash price of the hearing aid, were usually told by the dispenser that they would be allowed to make installment payments. However, the consumers were never told that finance charges would be imposed.

In virtually every instance, the dispensers' hearing aid purchase agreement failed to disclose the amount of the finance charge, or the annual percentage rate, or the number of installment payments, or much of the other material required by the terms of the Truth in Lending Act.

On most occasions, the interest assessed by the dispenser was usurious under West Virginia law.

In one instance, the consumer was told by the dispenser to continue making installment payments, despite having paid off the hearing aid contract several months before.

The final phase of the investigation was the most telling, and involved formal and informal interviews with current and former employees that performed hearing aid sales at the dealership.

These employees who were interviewed were, for the most part, not licensed to dispense hearing aids within the State of West Virginia. Rather, these individuals were designated as trainees who are permitted under West Virginia law to dispense hearing aids within the State despite not having satisfied any competency testing.

Every trainee interviewed stated that while they were testing for hearing loss, and sold and fit hearing aids, they had no conception of how to evaluate an individual's loss of hearing or determine when a person needed a hearing aid. Instead, the salespeople interviewed were primarily interested in closing a sale and receiving their commission.

When asked to define the most fundamental terms used within the profession, such as air conduction, bone conduction, speech reception level, most comfortable level, uncomfortable level, etc., these individuals were uniformly dumbfounded.

As a consequence to the findings made in the course of the investigation, the West Virginia Attorney General's Office filed a lawsuit alleging 26 separate counts. These included gross incompetence and negligence in the fitting and sales of hearing aids, high pressure sales and scare tactics, breach of expressed and implied warranties, inadequate servicing of consumers' hearing aids, and other complaints.

A second lawsuit was recently filed against an independent hearing aid dispenser doing business in West Virginia. The violation alleged in that lawsuit included taking money under false pretenses, and failing to provide customers a refund upon proper revision of their hearing aid purchase agreement.

We are also now undertaking investigations into two other hearing aid dispensers in the State of West Virginia.

I would now wish to focus my discussion on the problems facing the hearing aid industry and purchasers as a whole, and perhaps recommend some solutions.

I believe that the problems we've encountered in the prosecution of fraudulent and incompetent hearing aid dispensers are a microcosm of the problems facing the hearing industry as a whole.

First, the fraudulent representations relating to the benefits in using hearing aids, which are made in television and print advertisements, must be prohibited. Such advertisements give elderly consumers, grasping for solutions to their hearing problems, false hope and false expectations as to the technological ability of a hearing aid.

The advertisements, which are clearly targeted at the elderly, provide a sense of legitimacy to the unconscionable representations made by unscrupulous hearing aid dispensers.

Recently, an extensive multistate investigation in deceptive advertising was undertaken by 17 States through the offices of the National Association of Attorneys General. The investigation is focused on hearing aid manufacturers' advertisements that falsely represent the features or performance characteristics of their hearing aids.

The multistate working group was created for the purpose of enjoining hearing aid manufacturers from advertising about false and misleading performance claims.

The investigation is now nearing conclusion, and we hope it is in the process of settlement with the major hearing aid manufacturer.

Second, States' licensing and regulatory boards must prohibit individuals who have not undertaken competency testing from selling hearing aids with or without supervision by a licensed hearing aid dispenser.

In West Virginia, a trainee can sell a hearing aid only with supervision by a licensed hearing aid dispenser; however, the supervision requirement has been abused by many dealers, and in many instances, the supervision is so attenuated that it is nonexistent.

Also, I might add, in West Virginia, you are not required to have any special training in order to become an apprentice and undertake this work; while in contrast, if you wish to become a real estate agent in West Virginia, you must undergo over 100 hours of formal classroom training before being qualified to sit for the examination to become a real estate agent.

Third, manufacturers of hearing aids must bear responsibility for the shortcoming of hearing aid dealers, and refuse to design and sell hearing aids to dealers when the data submitted to the manufacturers indicates inadequate or incompetent testing.

Data reviewed by clinical audiologists during the course of the "Miracle-Ear" investigation revealed that many of the hearing aids sold by the manufacturers to dispensers were designed on the basis of insufficient information, and consequently, the aids had inadequate characteristics to meet the consumers' needs.

Senator PRYOR [resuming Chair]. Mr. Darling, could I interrupt you just a moment?

It's very likely that we may have a vote within about 30 minutes or so, and we do have a panel to follow. I'm wondering if I might ask you to conclude—

Mr. DARLING. Certainly.

The CHAIRMAN. I'm apologetic about interrupting you.

Mr. DARLING. No apology's necessary, sir.

The CHAIRMAN. Your full statement will be placed in the record.

Mr. DARLING. I might only add that—actually, to some comments made here before—is our concern with the abuse of the waiver of certification by a physician.

I believe that is one of our major and final concerns, and that's been addressed by some of the other witnesses.

With that, I'll conclude.

[The prepared statement of Mr. Darling follows:]

PREPARED STATEMENT OF
DONALD L. DARLING
DIRECTOR, ANTITRUST/CONSUMER PROTECTION DIVISION
WEST VIRGINIA ATTORNEY GENERAL'S OFFICE

BEFORE THE
SPECIAL COMMITTEE ON AGING
UNITED STATES SENATE

September 15, 1993

Senator Pryor, Senator Cohen and members of the committee: Thank you for this opportunity to discuss my views on the problems facing the hearing aid industry. I am testifying in my capacity as a designate of the Attorney General of the State of West Virginia and as a member state of the National Association of Attorney Generals (NAAG), although my views are not necessarily those of NAAG as a whole.

Hearing loss is an affliction that affects approximately twenty-eight million people in the United States, the majority of which are elderly. Elderly individuals suffering from hearing loss that refuse to purchase a hearing aid commonly withdraw from society because of their inability to socialize and communicate with others and because of societies' intolerance towards their affliction. Conversely, elderly consumers that decide to purchase hearing aids to compensate for their hearing loss are faced with the daunting and confusing task of choosing from whom to purchase a hearing aid. The skill and competency of hearing aid dispensers varies greatly in degree. As a result, elderly consumers purchasing hearing aids are frequently sold hearing aids that are not suited for their needs because of inadequate testing and fitting by incompetent and fraudulent dispensers.

The West Virginia Attorney General's Office has long been a firm advocate of protecting the rights of the elderly in consumer matters. West Virginia opened its first wide-scale investigation of hearing aid dispensers in May, 1992 at the request of elderly consumers and the West Virginia Board of Hearing Aid Dealers. The investigation focused on a Charleston, West Virginia based Miracle Ear franchise dealer doing business as Miracle Ear Hearing Aid Center. During the course of the investigation, thousands of documents were reviewed and analyzed by clinical audiologists and medical doctors and formal and informal testimony of numerous experts were consulted. After review and examination of audiograms, i.e. the results of hearing examinations, and review of patients' medical records, the medical experts uniformly concluded that the documents reflected incompetent testing and a

lack of reliability or validity of the tests as a whole, resulting in sales of unnecessary or inadequate hearing aids.

The investigation of the Miracle Ear franchise dealer also included interviews with elderly consumers filing complaints with the Consumer Protection Division of the Attorney Generals Office. In virtually every interview conducted the consumers stated that: "I could hear better without the hearing aid than with the hearing aid"; and "I have kept the hearing aid in my dresser drawer because the aid has not benefited my hearing". The majority of the consumers interviewed expressed dissatisfaction with the level of performance of their hearing aid. The consumers dissatisfaction seemed to stem primarily from the inflated expectations consumers had from the deceptive advertisements disseminated by the major hearing aid manufacturers.

Interviews with elderly hearing aid purchasers also led to the discovery that many elderly consumers were assessed excessive finance charges without their knowledge. Elderly consumers, unable to pay the cash price of the hearing aid, were usually told by the dispenser that they would be allowed to make installment payments. However, the consumers were never told that finance charges would be imposed. In virtually every instance the dispenser's hearing aid purchase agreement failed to disclose the amount of the finance charge, the annual percentage rate, the number of installment payments, or any other material credit term as required under the Truth in Lending Act. On most occasions the interest assessed by the dispenser was usurious under West Virginia state laws. In one instance a consumer was told by the dispenser to continue making installment payments despite having paid off the hearing aid several months previous.

The final phase of the investigation of the Miracle Ear franchise dealer was the most telling and involved formal and informal interviews with current and former employees that performed hearing aid sales at the dealership. The current and former employees interviewed were for the most part not licensed to dispense hearing aids within the state of West Virginia. Rather, these individuals were designated as trainees, that are permitted to dispense hearing aids within the state of West Virginia despite not satisfying any competency testing. Every trainee interviewed stated that while they tested for hearing loss and sold and fit hearing aids they had no conception of how to evaluate an individual's loss of hearing or determine when a person needed a hearing aid. Instead, the salespeople interviewed were

primarily interested in closing a sale and receiving their sales commission. When asked to define the most fundamental terms used within the profession such as: air conduction, bone conduction, speech reception level, most comfortable level, uncomfortable level and speech discrimination these individuals were dumbfounded.

As a consequence of the findings made in the course of the investigation, the West Virginia Attorney General's Office filed a lawsuit against the Miracle Ear brand dispenser alleging twenty-six distinct violations of state consumer protection laws. The principal violations alleged included: (1) Gross incompetence and negligence in the fitting and sales of hearing aids; (2) High pressure sales and scare tactics in connection with sales of hearing aids; (3) Breach of express and implied warranties; (4) Impermissible and excessive additional charges on hearing aid sales; (5) Inadequate servicing of consumers' hearing aids; and (6) Violations of federal and state preconditions to the sale of hearing aids.

A second lawsuit was recently filed against an independent hearing aid dispenser doing business as Hear America that engaged principally in home solicitation sales of hearing aids in West Virginia, Ohio, and Virginia. The violations alleged in that lawsuit included taking money under false pretenses and failing to provide consumers a refund upon proper rescission of their hearing aid purchase agreement. Further investigations into the business practices of West Virginia based hearing aid dispensers have been commenced against a Miracle Ear franchise dealer based in northern West Virginia and an independent hearing aid dispenser located in central West Virginia.

Rather than discuss the details of the State of West Virginia's litigation and investigations against hearing aid dispensers, I prefer to focus my discussion on the broad problems facing the hearing aid industry as a whole and recommend solutions to these problems. I believe that the problems I have encountered in my prosecution of fraudulent and incompetent hearing aid dispensers are a microcosm of the problems facing the hearing industry as a whole.

First, the fraudulent representations relating to the benefits of using a hearing aid which are made in television and print advertisements must be prohibited. Such advertisements give elderly consumers grasping for a solution to their hearing problems false hope and false expectations as to the technological ability of a hearing aid. The advertisements, which are clearly targeted

at the elderly, provide a sense of legitimacy to the unconscionable representations made by unscrupulous hearing aid dispensers. Such fraudulent inducements must be stopped through a cooperative enforcement effort by the state Attorney Generals, the Federal Trade Commission (FTC) and the Food and Drug Administration (FDA).

Recently an extensive multistate investigation into deceptive advertising practices of manufacturers of hearing aids was undertaken by seventeen states including the state of West Virginia. The investigation has focused on hearing aid manufacturers' advertisements that falsely represent the features or performance characteristics of their hearing aids. The multistate working group was created for the purpose of enjoining hearing aid manufacturers from advertising by false and misleading performance claims. Presently, the investigating states are in the process of negotiating a settlement agreement with a major hearing aid manufacturer.

Second, states' licensing and regulatory boards must prohibit individuals who have not undertaken competency testing from selling hearing aids with or without supervision by a licensed hearing aid dispenser. In West Virginia a trainee can sell a hearing aid only with supervision by a licensed hearing aid dispenser. However the supervision requirement has been abused by dealers and in most instances the supervision is so attenuated that it is nonexistent. Moreover, state regulatory boards must utilize their various disciplinary and administrative powers of suspension, revocation, and probation of dealer licenses more aggressively.

Third, manufacturers of hearing aids must bear responsibility for the shortcomings of the hearing aid dealers and refuse to design and sell hearing aids to dealers when the data submitted to the manufacturer indicates inadequate or incompetent testing. Data reviewed by clinical audiologists during the course of the Miracle Ear investigation revealed that many of the hearing aids sold by manufacturers to dispensers were designed on the basis of insufficient information and consequently the aids had inadequate characteristics to meet the consumers' needs.

Fourth, laws should be enacted at the state or federal level which ban or restrict home solicitation sales of hearing aids. Hearing tests conducted by door-to-door salesmen reeks of impropriety. Medical professionals within the hearing industry invariably agree that it is difficult if not impossible to get an accurate reading of a prospective user's hearing impairment when the testing is being performed in an individual's kitchen or living room. One suggested limitation on home solicitation sales of hearing aids would be to limit the amount of money the hearing aid dispenser could charge up front when engaging in a home solicitation sale of hearing aids. Alternatively, states should enact laws that require hearing aid dispensers to file a bond with regulatory board if they conduct home solicitation sales of hearing aids.

Finally and perhaps most important, the Food and Drug Administration's requirement that hearing aid dispensers not be allowed to sell a hearing aid to an individual eighteen years of age or older unless the prospective user has presented to the hearing aid dispenser or licensee a written statement signed by a licensed physician that states that the patient's hearing loss has been medically evaluated and the patient may be considered a candidate for a hearing aid should not be allowed to be waived by the prospective hearing aid user. The most pervasive problem I have encountered in my investigation of hearing aid dispensers is the falsification of waiver of medical evaluation forms and the omission to inform prospective users that it is in their best health interest to have a medical evaluation by a licensed physician prior to purchasing a hearing aid. Virtually every employee interviewed during the course of our investigations indicated that they did not inform prospective customers that it was in their best health interest to have a medical evaluation prior to purchasing a hearing aid. While elimination of the waiver of medical evaluation option may increase the costs of purchasing a hearing aid, it would virtually assure consumers that they are a proper candidate for a hearing aid and limit the number of unnecessary or inadequate sales of hearing aids.

I thank you for the opportunity to appear before you today. I would be happy to answer any questions you may have concerning West Virginia's enforcement efforts against hearing aid dispensers.

The CHAIRMAN. We very much appreciate your contribution to this hearing this morning.

And now, Ms. Sorkin.

STATEMENT OF DONNA SORKIN, EXECUTIVE DIRECTOR, SELF HELP FOR THE HARD OF HEARING PEOPLE, INC.

Ms. SORKIN. Mr. Chairman, I am Donna Sorkin, Executive Director of Self Help for Hard of Hearing People, or SHHH, a consumer organization representing a diverse constituency of hard of hearing Americans.

Millions of Americans in this country benefit enormously from the use of hearing aids. For a hard of hearing person, a well-fitted hearing aid can provide important quality-of-life improvements.

The technological improvements made in hearing aids in the past 10 years have further contributed to the positive aspects of hearing aid usage.

At the same time, it's important to realize that no hearing aid can restore normal hearing.

Further, in most instances, a hearing aid user derives significantly less benefit from a hearing aid in the presence of background noise.

Unfortunately, many people believe that a hearing aid is much like a pair of eyeglasses, and can ameliorate their hearing problem.

I would like to begin by providing you with a personal perspective on what it's like to lose your hearing.

Think of what it would be like to not be able to understand speech in a group of three or four people, to not be able to hear a child's soft voice—as an elderly person might not be able to hear their grandchild's voice—to miss half or more of what I am saying today, right now.

Recall the pleasures of going to the theatre or going to the movies, of watching television, of listening to music, or participating in family gatherings. All of those activities become arduous for someone who has experienced a hearing loss.

Think about how traumatic it would be if you needed to talk to a physician about a serious illness affecting a family member or about your own health, and you weren't sure that you would be able to understand what the doctor was saying.

All of those things happened to me when I was 35 years old, and it was a horrifying experience—how much worse it would have been if I were 65 and lived alone!

People need to be able to communicate in order to be able to control their lives, in order to maintain respect and dignity, and to enjoy simple pleasures. And when they lose their hearing, they are sometimes so desperate to make it right again, they will listen to unrealistic claims about hearing aids, and they will make purchases that they think will restore their hearing to what it was before.

The following comments are made in the hope that the problems that have plagued the industry will be corrected.

The experiences that are outlined here are based upon information provided to us by hard of hearing consumers and their families for the past 15 years.

Our organization spends considerable resources educating consumers because of the absence of standards and laws providing basic protection. We have helped turn around the lives of thousands of hard of hearing people.

Part of the success can be attributed to the use of hearing aids.

We know that the approach of educating consumers is not a solution to many of the problems that occur between the consumer and the provider.

It's been a frustrating experience for us because we're changing the behaviors of those consumers that we reach, but we're not changing the behaviors and attitudes of uneducated or unethical hearing aid dealers.

People that benefit from our resources can educate themselves, but it's more difficult to reach out to those who don't know about us.

For those reasons, regulatory statutes are needed to protect consumers.

Throughout my remarks, I will use the term "dispenser" to refer to all providers who dispense hearing aids—dealers, audiologists who dispense, and physicians who dispense.

The practice of identifying a hearing loss, and simply prescribing one or two aids is not appropriate. Dispensers may be well-intended, but they do not have enough training about hearing loss and how hearing aids fit into the process of rehabilitation.

Because hearing cannot be restored to normal, and because the condition is chronic, it affects one's ability to communicate on the job, at home, and in social settings.

The first problem that consumers run into is that it's difficult for them to understand where to enter the system.

People need a comprehensive diagnostic exam, not one that's simply limited to a measurement of which tones they can hear, and which tones they cannot.

Evaluations performed by qualified providers indicate how an individual functions in various "real world" settings, with and without a hearing aid. They also need to know what other kinds of assistance might help them.

Many people benefit from a hearing aid and speech reading lesson. Some need assistance with their speech. Some might be good candidates for a cochlear implant, and a great many benefit from joining support groups.

The 1977 FDA regulations for professional and patient labeling and conditions for sale of their hearing aids did not recognize these aspects of the rehabilitation process.

A hard of hearing person can walk into any retail establishment and be sold a device without an appropriate diagnostic assessment of the individual's needs or causes of the loss.

Because senior citizens with hearing loss are more likely—than younger adults or non-hearing impaired elderly persons—to be in poor health and to experience other disabling conditions, they are particularly vulnerable to in-home and mail order sales of hearing aids.

Ideally, we recommend to consumers that they be seen by a physician specializing in diseases of the ear prior to the fitting of a

first hearing aid; however, we believe in the consumers' right to waive this requirement.

For children, we believe in the existing regulations.

Many children have problems with chronic middle ear infections. We, therefore, believe that children should have routine otolaryngological examinations and audiological assessments prior to purchasing a hearing aid, whether or not it's a first time purchase.

The FDA regulation states that the hearing aid dispenser must inform the prospective user that the exercise of the waiver is not in the users' best health interest, and that the dispenser does not, in any way, actively encourage the prospective user to waive such a medical evaluation.

The existing problem of abuse stems partially from the fact that consumers are not aware of the importance of this measure, or they are unaware of what they have signed.

One corrective measure would be to require all dispensers to more fully explain the purpose of a medical exam prior to offering the written waiver option.

Further, the waiver text should be printed as a separate document.

As we understand the current regulations, any physician can sign off on the required medical evaluation. There's no requirement that an individual see a specialist in diseases of the ear or hearing.

Persons living in rural regions and even in certain urban areas do not have ready access to otolaryngologists, and are forced to see family doctors who have no special knowledge of hearing loss. We hear from consumers that their physician, often a family doctor, told them that they have nerve deafness, and nothing can be done to help them.

In these instances, in the absence of access to an otolaryngologist, hard of hearing persons are better served by an exam performed by an audiologist.

We encourage all consumers who think they have a hearing problem, and wish to purchase a hearing aid for the first time, to have a diagnostic evaluation from an audiologist. Such an evaluation would, in most cases, identify medical causes, and then an appropriate referral could be made to an otolaryngologist.

Many consumers tell us that the cost of even modest hearing aids is excessive, and not commensurate with the technology involved in providing amplification.

In the absence of third-party insurance for hearing aids, many consumers simply cannot afford the devices.

In the absence of regulations, dispensers can set their own policy concerning whether or not a buyer is entitled to a full refund.

While hearing aid dispensers receive return privileges from their suppliers of hearing aids, they often resist efforts to establish a standard extending this right to the end user, even when the manufacturer offers a full return for the aid.

In some cases, if the dispenser determines the aid to be beneficial, regardless of the consumers' opinion, no return is allowed.

Even when dispensers have the best of intentions, consumers need time to work with the provider to make adjustments to a hearing aid, or in some cases, to try different hearing aids.

We believe a federally mandated 60-day trial period with a buyers' right to cancel provision should be initiated.

In conclusion, I'd like to emphasize that most consumers with a hearing loss are elderly, and they're vulnerable to a system that lacks basic consumer protection against misleading advertising, unethical sales practices, and the absence of standards for diagnostic testing and fitting of hearing aids.

Not only are consumers faced with excessive costs for hearing aids, but there's no protection against dispensers who have unfair or nonexistent warranties and return policies.

To further compound these problems, when elderly consumers are not satisfied with the costly devices, there is often no clearly defined mechanism for them to file a complaint.

We believe that all potential hearing aid users should see an otolaryngologist, but we support the informed adult consumers' right to waive the medical evaluation.

Consumers should have audiological diagnostic evaluations to assess their individual rehab needs which go beyond the hearing aid.

Thank you for this opportunity to comment.

[The prepared statement of Ms. Sorkin follows:]

TESTIMONY

before the

Senate Special Committee on Aging

September 15, 1993

presented by

Donna L. Sorkin

Executive Director

SELF HELP FOR HARD OF HEARING PEOPLE, INC. (SHHH)



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September 15, 1993

Senator William S. Cohen
Ranking Minority Member

Senator David Pryor
Chairman

United States Senate
Special Committee on Aging
Room SDG-31
Washington, DC 20510-6400

Good morning. My name is Donna Sorkin and I am testifying on behalf of Self Help for Hard of Hearing People, Inc. (SHHH), a consumer organization representing a diverse constituency of some 23 million Americans with some form of hearing impairment¹. I appreciate the opportunity to comment on this urgent and timely issue. Because the incidence of hearing loss increases dramatically with age, the majority of persons with hearing loss are over age 55; likewise the majority of our membership is composed of senior citizens with hearing loss.

Millions of people in this country benefit enormously from the use of hearing aids. For a hard of hearing person, a well-fitted hearing aid can provide important quality of life improvements. The technological improvements made in hearing aids in the past ten years have further contributed to the positive aspects of hearing aid usage.

At the same time, it is important to realize that no hearing aid can restore normal hearing. Further, in most instances a hearing aid user derives significantly less benefit from a hearing aid in the presence of background noise. Unfortunately many people believe that a hearing aid is much like a pair of eyeglasses and can ameliorate their hearing problem. In some cases, advertising and marketing practices of the industry combined with attitudes by

¹ This figure is based upon the latest National Health Interview Survey from the National Center for Health Statistics (NCHS).

some dispensers² that they can "fix" the problem leads to disappointment by the hard of hearing consumer. A great many hearing aids end up in dresser drawers leaving the consumer with negative attitudes about all hearing aids and about the industry in general.

The following comments are made in the hope that the problems that have plagued the industry will be corrected. We want hard of hearing people to seek the best help possible, but we also want them to have realistic expectations about hearing aids so that they will derive benefit from hearing aid usage.

The experiences that are outlined here are based upon information provided to us by hard of hearing consumers and their families for the past 15 years.

Many persons experience a long period of denial. It is not unusual for an individual to wait 10 years to purchase a hearing aid once they have determined they have a hearing loss. Taking that first step to enter the hearing health care system can be a bewildering experience.

We spend a great amount of our resources educating consumers because of the absence of standards and laws to provide basic protection for them. We provide written materials, peer support, and educational activities to inform consumers about how to protect themselves when they go to purchase a hearing aid. We have helped turn around the lives of thousands of hard of hearing people; part of that success can be attributed to the use of hearing aids and other assistive technology.

We know that the approach of educating consumers is not a solution to many of the problems that occur between the consumer and the provider. It has been a frustrating experience for SHHH because we are changing the behaviors of those consumers that we reach but we are not changing the attitudes and behaviors of uneducated or unethical hearing aid dealers. Also, because of the large and growing number of people with a hearing loss in the United States, we do not have the resources to address widespread abuse.

The persons that benefit from our services have the wherewithal, or resources, to reach out and to educate themselves. It is more difficult to identify and help those who really need help; those who are isolated and lack the resources they need to advocate on their behalf. For these reasons, regulatory statutes are needed to protect consumers against misleading advertising, unethical sales practices and the lack of standards for testing and fitting of hearing aids.

² The term "dispenser" refers to all providers who dispense hearing aids- hearing aid dealers (or Hearing Specialists, the term designated by the hearing industry); audiologists who dispense, as well as physicians who dispense. Abuse in the industry can and does occur by all dispensers. However, based upon the feedback we have received from consumers over the past 15 years, hearing aid dealers (non-audiologists) are involved in a significant portion the abuses.

TESTING, DIAGNOSING AND FITTING OF HEARING AIDS

The practice of identifying a hearing loss and simply prescribing one or two aids is not appropriate. Many dispensers' are well intended. However, some do not have enough training about hearing loss and how hearing aids fit into the process of rehabilitation. Because hearing cannot be restored to normal, and because the condition is chronic and insidious, it affects one's ability to communicate on the job, at home and in social settings. Often because of the negative effect that hearing loss has, there are psychosocial consequences to hearing loss. Therefore, "treatment" may justify interventions from a number of allied professions, such as audiologists, psychologists or vocational counselors, not just a physician and a dispenser.

The first problem that consumers run into when they decide to do something about their hearing loss is that it is difficult for them to understand where to enter the system. These persons need a comprehensive diagnostic evaluation; one that will not be limited to the identification of the loss (e.g., measurement of which pure tones they can and cannot hear). Evaluations performed by qualified providers indicate how a given individual functions in various "real-world settings" with and without a hearing aid and what other types of assistance might help the person cope with the hearing loss. Then, the individual will have enough information to help them better understand and adjust to their hearing loss and make decisions about what further assistance might be helpful. Presently, aids are being sold with no visit to an audiologist for a diagnostic evaluation and no visit to a doctor.

Many people benefit from a hearing aid and speechreading lessons, some need assistance with their speech, some might be good candidates for a cochlear implant, and a great many benefit from joining support groups. Many hard of hearing people are elderly and also have visual impairments and other health conditions; in these instances the hearing loss may be primary or secondary to other problems.

The 1977 FDA regulations for professional and patient labeling and conditions for sale for hearing aids do not recognize these aspects of the rehabilitative process. A hard of hearing person can walk into any retail establishment and be sold a device, without an appropriate diagnostic assessment of the individual's needs. So, the abuses of the medical waiver are only one aspect of the problem. Dispensers who abuse this law and other regulations need to be made accountable via stringent enforcement and disciplinary actions.

In-Home and Mail-Order Testing and Sales Practices

Elderly consumers, who make up the majority of people in the United States with hearing loss are most often targeted by hearing aid dealers marketing their products. Senior citizens with hearing loss are more likely than younger adults or non-hearing impaired

³ Although this term includes audiologists and physicians, we recognize that most of the abuses occur between the consumer and the hearing aid dealer (non-audiologist).

elderly persons to be in poorer health and to experience other disabling conditions.

Elderly persons are particularly vulnerable to in-home and mail-order sales of hearing aids. No other device of this nature, such as glasses or dentures are sold at home. Often, elderly consumers will assume they are receiving ethical treatment because they have come to expect a certain standard of care from their eye doctor and optometrist. Some dispensers wear white jackets and may knowingly lead consumers to believe they are doctors⁴.

Sixty percent of persons with hearing loss have progressive or fluctuating losses, so it is important to purchase a hearing aid based upon the results of a current audiological evaluation; this cannot be performed in the home or through the mail.

"Free Hearing Tests" Advertisements

Many elderly people are on limited or fixed incomes and are attracted to advertisements of "free hearing tests." Related to this practice is the practice of sending the consumer "appointments" through the mail for their "free hearing test"-- appointments they did not make.

First time buyers do not understand that such tests by dealers who are not audiologists are "free" only because the vendor does not have credentials that enable him/her legally to perform or charge for diagnostic testing. In these cases, consumers will frequently pay more for the hearing aid when tests are "free"; they simply charge more for the aid and don't charge for the test.

One corrective measure could be requiring an "unbundled" itemized invoice which would reveal the inflated price of the hearing aid when "free" tests are offered.

HEARING AIDS AND BACKGROUND NOISE VS. SPEECH DISCRIMINATION

Consumers are often led to expect that a hearing aid will eliminate or "filter" background noise. They are led to believe that the latest technology can restore their hearing and consequently are not satisfied with the hearing aid when it does not allow them to understand speech in noisy environments.

Hearing aids with special circuitry may improve speech discrimination in some situations. But no hearing aid can enable a hard of hearing person to function like an individual with normal hearing.

For many persons, hearing aids can improve their ability to understand speech, but only if the aids are properly prescribed and fitted. In addition, follow-up and counseling on how to use, maintain and adjust to the hearing aid(s) is very important. Persons with hearing loss need to know that background noise cannot be eliminated (without the use of assistive listening devices and systems), and in most cases, they simply need to learn to live with it. Killion and Vilchur (1993) for example, pointed out that 80% of the hearing aids sold in 1991 used circuits that cause excessive distortion in noisy settings which either do not help much or make

⁴ Consumers have told us that since the dealers showed up wearing a white jacket and "talking like a doctor", and call their office a "clinic", they assumed the dealer was a doctor and therefore signed the medical clearance waiver because they believed they already received a medical evaluation.

things worse for the hard of hearing consumer.

TRUTHFUL ADVERTISING AND LABELING PRACTICES

We advocate for truthful advertising and labeling because we know that hard of hearing people can be helped, if appropriate testing, fitting and rehabilitation services are made available. We feel that advertising can be positive and truthful at the same time. We are very concerned that, in our efforts to promote better consumer protection, we might give consumers the impression that hearing aids cannot help them. We know that in most cases this is not true and want to continue to encourage consumers to seek help when they think they have a hearing loss. We know that hearing aid technology has improved over time and will continue to improve in the future. Our job will be easier if we can insure them protection from unethical practices coupled with positive encouragement to try technology.

MEDICAL CLEARANCE OR WAIVING FOR FITTING/PURCHASE OF AN AID

Ideally, we recommend to consumers that they be seen by a physician specializing in diseases of the ear, prior to the fitting of a first hearing aid. However, we believe in the consumer's right to waive this requirement. For children, we agree with the existing regulations. Many children have problems with chronic middle ear infections; we therefore believe that children should have routine otological examinations and audiological assessments prior to purchasing a hearing aid-- whether or not it is a first-time purchase.

The FDA regulations (section 801.421. Hearing aid devices; conditions for sale) state that the hearing aid dispenser must inform the prospective user that the exercise of the waiver is not in the user's best health interest and that the dispenser does not in any way actively encourage the prospective user to waive such a medical evaluation. The existing problem of abuse stems partially from the fact that consumers are not aware of the importance of this measure, or they are unaware of what they have signed.

One corrective measure would be to require all dispensers to more fully explain the purpose of a medical examination prior to offering the written waiver option; and that further, the waiver text be printed as a separate document.

As we understand the current regulations, any physician can sign off on the required medical evaluation; there is no requirement that an individual see a specialist in diseases of the ear or hearing. Persons living in rural regions and certain urban areas of the United States do not have ready access to otolaryngologists and are forced to see family doctors who have no special knowledge of hearing loss. We hear from consumers that their physician, often a family doctor, told them that since they have "nerve deafness", nothing can be done to help them. In such instances, in the absence of access to an otolaryngologist, hard of hearing persons are better served by an exam performed by an audiologist. We encourage all consumers who think they have a hearing problem and wish to purchase a hearing aid for the first time to have a diagnostic evaluation from an audiologist. Such an

evaluation would, in most cases, identify medical causes⁵ and then an appropriate referral could be made to an otolaryngologist.

Presently, the FDA does not recognize the audiologist as a possible point of entry into the hearing health care system. Consequently, if consumers do not sign the waiver, they can go to a family doctor and then go to an audiologist, and then to a dispenser if the audiologists does not dispense. State laws that recognize the value of audiologists in this role should not be preempted by the FDA rule.

COSTS OF HEARING AIDS AND THIRD PARTY PAYMENTS

Most consumers that we come in contact with, including those who complain to us in writing, feel that the cost of even modest hearing aids is excessive and not commensurate with the technology involved in providing amplification. In the absence of third-party insurance coverage for hearing aids, many consumers simply cannot afford the devices.

Another problem to address, concerns dispensers who tell buyers that Medicaid or Supplemental Security Income (SSI) will pay for aids even though SSI does not pay and Medicaid pays only in certain states. For elderly persons on limited or fixed incomes, the cost of getting a hearing assessment, a medical evaluation and then a hearing aid comes from their meager savings. If the aid is broken or needs to be replaced, often they are financially unable to replace the aid. For persons who do not benefit from the aid and for which there is no warranty, trial or return policy, the financial loss can be devastating.

HEARING AID RETURN POLICIES, WARRANTIES

Only 13 states have legislatively enacted hearing aid return provisions⁶. Prior attempts to mandate a return option were, after extended "study", rejected. The FTC considered a federally mandated hearing aid buyers right to cancel provision. The rationale provided by the industry was the mandate was not needed since many dealers voluntarily offer a trial option. Our concern is not those ethical dispensers who offer trial or rental options, even in the states where it is not mandated. Our concern is for the first-time purchaser of a hearing aid who is victimized by hearing aid dispensers with ethics and practices that are only financially motivated.

For example, in the absence of regulations, dispensers can set their own policies concerning whether or not a buyer is entitled to

⁵ 5-10 percent of hearing losses are attributed to medical causes or require medical intervention by physicians who specialize in diseases of the ear.

⁶ According to The International Hearing Society (Oct., 1992), the following stipulate a buyer's right to cancel: CA; CT; KY; ME; MN; NH; OR; TN; TX; VT; VA; WA and W.VA. The majority of these statutes impose a 30 day right of return.

a full refund. While hearing aid dispensers receive return privileges from their suppliers of hearing aids, they often resist efforts to establish a standard extending this right to the end user. Even when the manufacturer offers a full refund for return of the aid, in some cases, if the dispenser "determines the aid to be beneficial," regardless of the consumer's opinion, no return is allowed.

Even when the dispensers have the best of intentions, consumers need time to work with the provider to make certain adjustments to a hearing aid(s), or in some cases to try different hearing aids. The hearing aid user needs time to: test how the hearing aid works in different communication environments; determine whether the mold is appropriate (some people are allergic to the plastic and find they need hypo-allergenic materials); determine sensitivities to loud sounds (commonly associated with sensori-neural hearing loss); and to determine whether they can properly interface with a particular assistive device. Also, many consumers are sold hearing aids without a telecoil¹, and find that they can function much better with a hearing aid that has a T-coil.

For these reasons, consumers need extended warranties to cover supplies, adjustments, and any necessary repairs and a federally mandated 60-day trial period, with a buyer's right to cancel provision.

COMPLAINT HANDLING AND REGULATORY BOARDS

Most states still allow the regulated interests to dominate the regulatory board. Some state boards given the authority to mediate disputes are composed primarily of dispensers resulting in "the fox guarding the chicken coop" situation. Although most boards have enough authority to oversee and discipline unethical dispensers, they seldom use their powers. Consequently, consumers do not know where to turn when they have a complaint. They might appeal to the state board of audiologists (who also must have a separate license to dispense), or a state board of hearing aid dealers (specialists).

We strongly believe that people with hearing loss and providers who do not have a financial stake in the sale of hearing aids should be represented on boards that mediate complaints. Audiologists and physicians specializing in the treatment of ears should have representation that is at least equal to that of hearing aid dispensers (non-audiologists). Consumers who are knowledgeable about hearing aids and assistive listening technology should have representation that is equal to that of audiologists and physicians.

Consumers need easier procedures for making complaints. For example, we know that those states with 800 numbers or widely

¹ The telecoil is a special feature in the hearing aid which permits the user to move the switch to "T" and talk on the telephone, or to use with other assistive device. The "T" switch can link the hearing aid to sources of electromagnetic energy, the most common of which are the audio loop system, or an assistive listening device. The purpose of the telecoil then is to permit direct communication via the electromagnetic source without interference from other sources.

publicized numbers receive the most complaints. Some states which rigidly insist on written complaints make it very difficult for persons with hearing loss, especially those who are elderly, to make complaints. Reforms are needed so that consumers have an accessible and "friendly" complaint handling system with a philosophy that is consumer service oriented, staffed by persons who can advocate on behalf of hard of hearing consumers.

CONCLUSION

Most consumers with a hearing loss are elderly and are vulnerable to a system that lacks basic consumer protection against misleading advertising, unethical sales practices, no standards for diagnostic testing and fitting of hearing aids. Not only are consumers faced with excessive costs for hearing aids, but there is no protection against dispensers who have unfair or non-existent warranties and return policies. To further compound these problems, when elderly consumers are not satisfied with the costly devices, there is often no clearly defined mechanism for them to file a complaint.

SHHH feels that all potential hearing aid users should see an otolaryngologist, but we support the informed adult consumer's right to waive the medical evaluation. Consumers should have audiological diagnostic evaluations to assess their individual rehabilitation needs which go beyond the hearing aid. We feel that the present FDA law preempts the critical role of audiologists play in the rehabilitation process.

Thank you for this opportunity to comment here today. If I can be of any further assistance concerning this issues, please do not hesitate to contact me.

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Senator COHEN [assuming Chair]. Thank you very much, Ms. Sorkin. Your testimony has been very helpful to us.

I have just a few questions, since we have one panel to go.

Let me first state, for the record, that Senator Pryor had to retreat once again to the hearings on NAFTA with Secretary Warren Christopher, who's now testifying, and has asked me to proceed to the conclusion of the hearing. He will read all of your statements in their totality.

Mr. Darling, my understanding is that you have instituted legal action against the company distributing "Miracle-Ear" in Charleston.

Mr. DARLING. Yes. That's right.

Senator COHEN. Is that of a civil nature, or—

Mr. DARLING. It is of a civil nature. Our powers are purely civil.

Senator COHEN. Right. Now, do you know whether or not "Miracle-Ear" is still supplying the Charleston dealer with "Miracle-Ear" products?

Mr. DARLING. They are not at this time. The franchise has been terminated.

Senator COHEN. My understanding is—and I want to make this clear for the record—that "Miracle-Ear" is manufactured in Minnesota.

Senator Durenberger wanted me to indicate that "Miracle-Ear" has, in fact, withdrawn sponsorship from this particular dealer.

My understanding is that this dealer is, nonetheless, still operating. Is that correct?

Mr. DARLING. That is correct, Senator.

Senator COHEN. But not supplying "Miracle-Ear" products?

Mr. DARLING. No. They are no longer supplying "Miracle-Ear" products.

Senator COHEN. All right. Now, when you talk about the breach of warranty, what sort of warranties are being made, and what are the breaches that they are being sued for?

Mr. DARLING. The warranty being fit for the particular purpose—that is to restore hearing.

That's a warranty incorporated in West Virginia law, and incorporated in the Uniform Commercial Code—that while there may be expressed warranties about the operation or the ability to operate, which may also be breached, the major field of breach is the inability to provide the service that the product is purchased for—that is, the hearing is not restored, or the hearing is not corrected to an acceptable level.

Senator COHEN. And what about inadequate servicing? They are also being sued for breach of contract in that regard?

Mr. DARLING. Yes, a failure to repair, or failure, in some instances, to adequately fit or to re-fit when they're inappropriate.

We have one consumer whose hearing aid was so poorly fitted that it continually fell out of her ear, and in fact, once fell under a truck, and it took four people to find it.

Senator COHEN. Were there a great deal of in-home sales associated with this particular case?

Mr. DARLING. Yes. There were a large number of in-home sales, and they proved to be very problematic.

Often, there was testing done in the home, and there was a great deal of noise available—people living by busy highways, or it was done with air conditioners, or refrigerators, and children making noise.

Senator COHEN. Were there any violations of current State and Federal laws during the course of these home solicitations and sales?

Mr. DARLING. Well, we believe there were violations—yes, Senator, and additionally, violations of the 30-day period for returns and refunds.

Senator COHEN. All right.

Back in 1985, the FTC terminated a rule-making proceeding it had initiated that would have, among other things, mandated a 30-day trial period—not a 60-day, but a 30-day trial period. Ms. Sorkin—and the FTC vote to drop the rulemaking was premised on a survey, that they conducted, that found that a high percentage of hearing aid buyers were satisfied with their purchases. Yet, here we are just a few years later, and your survey indicates something quite to the contrary.

The question I have is, are consumers becoming more dissatisfied, because we're a dissatisfied lot, or have the practices on the part of either the manufacturers or the dealers raised a level of expectation to the point where now consumers are reflecting, as shown in your survey, their dissatisfaction?

Dr. DIXON. Well, Senator, I can't give you a scientific answer, but personally, I would think—for one thing, our population is becoming older—we are aging—and you know that the older persons are the greater users of hearing aids, so we have a larger population using these aids, so we have a greater potential for expressions of satisfaction or dissatisfaction.

Another thing is the media coverage, such as these ads that we have here. People read these things, and it leads them to expect that they're going to get perfection—they're going to get their hearing back to where it once was.

When they don't get that, then they are dissatisfied.

I think those factors might have some bearing on the volume of complaints that we're getting nowadays.

Senator COHEN. So if the expectations are not raised quite as high as they are by ads such as these, you'd have less of an expression of dissatisfaction? That people would come to expect a lower level of hearing, or ability to detect differences in tone, or whatever?

Dr. DIXON. Yes. They would recognize that—they would get the real facts. They would know what they cannot get from a hearing aid, as well as what they can get.

I think that it's very important that consumers be educated.

AARP has one of its major objectives educating the public on issues such as this, and we have put out this bulletin—a product report on hearing aids came out in 1989, and it really guides the consumer through the process of trying to get a hearing aid.

Senator COHEN. Ms. Sorkin, what kinds of advertising claims should the consumer view with great skepticism?

Ms. SORKIN. The skepticism is a result of what we've all been talking about—the fact that these marketing practices lead you to believe that your hearing will be restored to normal.

In fact, getting used to a hearing aid takes a long period of time, and involves more than just learning to change the dials.

Many consumers benefit from using technology like this—the assistive device system that you have in the room, like we have today. Most people with a hearing aid would have difficulty hearing you in this kind of a room, so you have to get accustomed to a variety of different settings, and you need to be able to try different aids to be able to find the one that's right for you.

Too often, we go in, we're given a particular aid, we go home with that, and we try to use it in a 2-week period or a 30-day period—which is really not enough, having been through this process myself several times.

It's a long, complicated process that needs someone who understands your needs to work with you, and that leads to consumer dissatisfaction—when you don't get what you want from the device at the end of the period.

Senator COHEN. So red flags or red lights should start going off whenever you see an ad that says, "We can restore your hearing," or "You'll be able to discriminate human voices from other types of sounds with great clarity." Are those the kinds of ads that we should be skeptical of, and should we insist on more information?

Ms. SORKIN. I think, as I said in my earlier comments, some of us want our hearing back so desperately that when someone tells us that this is going to help you get your hearing back, and you haven't been educated on the process, you grab at the first thing that someone gives you.

I think that's really what leads us to a lot of the problems that have occurred, and will continue to occur until we educate people about what a hearing aid can do for you.

Senator COHEN. Well, let me just say, for the benefit of those who are here, I suspect that our education is going to be a continuing education because as technology continues to improve, we are going to see some of these claims that are currently being made, actually achieved.

I know that we are moving toward digital technology in the use of hearing aids, to the extent that digital technology can, in fact, separate or heighten certain types of noises versus those of others, and I think that we have to be made aware of those technological advances and that those claims have to be substantiated.

I know that several of my colleagues in the Senate, for example, who wear hearing aids have bought some new devices which are hand-held, which, in fact, will accentuate certain types of sounds for them. It requires great training and a good deal of time to adjust to, but they are attempting to educate themselves in that process.

I think, as far as this hearing is concerned, we want to alert our senior citizen community, in general, and others who might suffer a hearing impairment that they should beware. That they should be wary. That they should insist upon certain information, and that they should, in fact, consult a specialist; be it a physician, or

a specialist, or an audiologist. But they should get more information.

We have to insist on compliance with the warranties that are made. Number one, the consumer should look at those warranties, and number two, should insist that they be, in fact, fulfilled, as well as the service requirements that are represented to the purchaser.

I guess you would all agree with that?

Dr. DIXON. Certainly.

Senator COHEN. Well, in order to allow for the third and final panel to make its presentation, I'm going to conclude my questioning. I may have some additional ones, and I'll ask you to submit your answers for the record.

But before letting you go—Senator Pressler, did you have any questions you'd like to ask?

STATEMENT OF SENATOR LARRY PRESSLER

Senator PRESSLER. Mr. Chairman, I shall place my statement in the record.

I want to commend the witnesses and you for holding these hearings.

I also have a letter from the President of the South Dakota Hearing Aid Dealers' Association, and I would like to ask you now to consent to placing that in the record.

Senator COHEN. Without objection, your prepared statement will appear in the record.

[The prepared statement of Senator Pressler along with a letter from Robert D. Reierson, President, South Dakota Hearing Aid Dealers Association follows:]

PREPARED STATEMENT OF SENATOR LARRY PRESSLER

Mr. Chairman, thank you for conducting today's hearing. As always, these hearings serve a dual purpose. They address a specific need or problem facing senior citizens. In addition, they serve as a useful educational tool to the general public.

As some have testified today, the hearing aid industry does have problems. Not all of the 23.5 million Americans with hearing loss have received quality care. We all share the same goals. We must guarantee safety, competence, and integrity in the industry.

Many part paths when we begin to discuss ways to fix these problems. We can't attempt to fix these problems while causing problems for most of the hearing impaired and the hearing aid industry. I want to issue a word of caution—new Federal regulation won't work. I want to caution regulators. Remember this simple principle. One shoe does not fit all sizes. One comprehensive Federal policy won't fit the needs of everyone in the various States. States should be allowed to regulate this industry.

Let me share a few facts with you. In South Dakota audiologists and hearing aid dispensers must be licensed by the State. They are required to take a written and practical examination. When this exam is passed they are issued a license. Then, they are able to sell and make ear impressions.

In the last 15 years only 2 complaints have been filed against an audiologist or hearing aid dispenser. I don't view these numbers as alarming. Certainly they don't illustrate the need for new Federal guidelines.

There are 30 audiologists in South Dakota. They are located in the 6 largest counties. If Federal regulations only permitted an audiologist to test for hearing loss and fit hearing aids—individuals in 61 South Dakota counties would lose access to care.

There are 47 licensed hearing aid dispensers in South Dakota. They are providing needed services in many of the lesser populated areas.

In addition, such a regulation would result in the loss of nearly 250 jobs.

As many of you know, recruiting medical professionals is one of the biggest challenges rural states like South Dakota face. We need the flexibility to utilize physi-

cian assistants in conjunction with physicians. We also must be permitted to utilize hearing aid dispensers in conjunction with audiologists and physicians. States like South Dakota will not enact careless regulations. We need the flexibility to meet the unique needs of our state.

Please don't misinterpret my comments. Some individuals with hearing aids have not been properly served. This problem must be addressed. However, I firmly believe that additional regulation will only create problems.



Receiving / in memo /

8 September 1993

To: The Honorable Larry Pressler
United States Senate
Washington, D.C. 20510-4703

Dear Senator Pressler:

I'm writing you in regards to your position on the Senate Special Committee on Aging. As President of the S.D. Hearing Aid Dealers Association, composed of 47 members, we are opposed to the ideas of Dr. Kessler of the FDA. This concerns the hearing aid dispensers regulations that Dr. Kessler would like to impose at the Sept. 15 committee meeting.

- 1) That all people must be tested by an audiologist before they can purchase a hearing aid.
 - 2) Only audiologists and physicians can prescribe hearing aids.
- Dr. Kessler will be releasing these facts to you on Sept 15, 1993 when the committee meets.

Since South Dakota is a rural community, this sort of constraints would bear undue hardships to not only the hearing aid dispenser but also to the hard of hearing consumer. Many other states would also have similar hardships.

If a law mandating that only an audiologist may test for and prescribe hearing aids, a void will be created in the Hearing Health Care Field. I personally, along with 46 other businesses would be legislatively out of business. This in turn effects our present and future cliental looking for a place to receive hearing health care. To sum it up;

- 1) There are only 30 audiologists in the state, of which only 25 of them dispense hearing aids.
- 2) There is only one college in our state that provides the needed education to become an audiologist.
- 3) This college is not even accredited by American Academy of Audiology.
- 4) Medical expenses will go higher for the hard of hearing public.
- 5) This would burden the person looking for hearing health care to the point they would give up looking for help.

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South Dakota Licensed Hearing Aid Dispensers

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We feel these mandates that are forth coming from Dr. Kessler are unnecessary!

- 1) South Dakota has a state board examination to prove competence of hearing aid specialists.
 - A) A written examination; to prove knowledge.
 - B) A practicum examination; in which an individual must be able to perform functions associated with the fitting of hearing aids. I.E.
 - 1) Pure tone testing; Air/ Bone
 - 2) Speech testing; SRT, MCL, UCL & Discrimination Scores.
 - 3) Otoscopic examination of the ear
 - 4) Taking a proper ear impression.
- C) Licensee must receive at least 12 hours of continuing education a year to upgrade their knowledge.

In South Dakota, audiologists are not licensed to practice audiology. Audiologists do have to be licensed to dispense hearing aids. There are 30 audiologists in our state, at present they are not licensed to practice audiology in our state. Audiologists must be licensed to dispense hearing aids. A poll was taken of the 30 audiologists and 25 responded:

- 1) 15 said they needed to be licensed to dispense hearing aids.
- 2) 6 opposed licensing to dispense hearing aids.
- 3) 4 abstained

This shows me not only do audiologist need to be licensed to practice audiology but must need to obtain a license to dispense hearing aids.

Hearing Aid Dispensers have shown the foresight of the need to protect the consumer by creating a licensing board with stringent regulations controlling their profession in the hearing health care field. In our state we have had only 2 registered complaints over the past five years and those complaints were resolved by the dispensers involved when made aware of the complaint. Due to the above reasons, I respectfully request that you lobby and vote against this measure.

Thank you for your time and we will be waiting to hear from you.

Sincerely;

Robert D. Reierson

Robert D. Reierson
President, S.D. Hearing Aid Dealers Association

Senator PRESSLER. I have one brief question to the panel.
 In your views, who should be permitted to test hearing and fit hearing aids?

There's some concern in my State that excessive Federal regulation may result in decreased service or access in some rural areas. Do any of you have a comment on that?

Ms. SORKIN. We feel that the initial testing and fitting of the hearing aid should be done by a certified audiologist.

Once that audiologist has done a fitting of an individual, the actual dispensing of the hearing aid can be done by someone else. But the initial analysis of how that person functions and what kind of hearing assistance might best help them should be done by an audiologist.

Senator PRESSLER. Thank you very much.

Mr. Chairman, I shall place all these documents in the record.

Senator COHEN. Senator Feingold?

STATEMENT OF SENATOR RUSSELL FEINGOLD

Senator FEINGOLD. Thank you, Mr. Chairman. I apologize for not being here earlier; it was my turn to preside over the Senate, as the freshmen are asked to do, and I got over here as fast as I could.

I'm very pleased that the Committee is holding this series of hearings, and that today's focus is on the hearing aid industry.

I also want to say that I'm very pleased that the AARP has chosen today to release its report on hearing aids. The work done by the AARP is quite telling, and I think it reveals the magnitude of the problem before us today.

I will ask one question, but if I may, just briefly, comment that when I was Chairman in Wisconsin of the Wisconsin State Senate Committee on Aging, our Committee learned that hearing loss and other communicative disorders such as speech impairment and related language deficiencies affected over 500,000 people in Wisconsin alone, which strikes me as the same number we have of people who are actually uninsured in Wisconsin—it's that large of a number in terms of health insurance.

The invisible disability of hearing loss afflicts all age groups and brings with it significant social and psychological problems, as the hearing impaired withdraw from coworkers, neighbors, friends, and even family members.

I hope today's hearing will lay the groundwork for additional work to address this significant health care issue, and I'd ask unanimous consent that the remainder of my statement be placed in the record.

Senator COHEN. Without objection, your prepared statement will appear in the record.

[The prepared statement of Senator Feingold follows:]

PREPARED STATEMENT OF SENATOR RUSSELL D. FEINGOLD

Mr. Chairman, members of the Committee, I am delighted that the Committee continues its superb series of hearings this session with today's focus on issues in the hearing aid industry.

I am particularly pleased that as a part of this hearing, the American Association of Retired Persons (AARP) is releasing its report on hearing aids. The work done by AARP is telling, and reveals the magnitude of the issues before us today.

According to the AARP report, there are over 23 million people in our country suffering a hearing loss, with an estimated 14 million of them over the age of 65.

Though hearing aids represent the third most widely used assistive devices, following canes and glasses, AARP reports that only about 1 person in 5 who could benefit from a hearing aid actually wears one.

It is clear that the hearing aid market is both substantial, and has the potential for being much larger. And with an average price of \$600 for each hearing aid, the potential for sales in the tens of billions of dollars is easily seen.

Given the possible vulnerability of a portion of the large hearing aid market, there is potential for abusing consumers.

Today's hearing will explore some of those abuses that have taken place, and, I hope, will provide this Committee with some guidelines in pursuing ways to combat those abuses.

In addition to hearing about how to address consumer abuses, I am also interested more generally in how to make hearing assistive devices more accessible to those who need them. As AARP notes, neither Medicare nor most health insurance policies cover the cost of hearing aids, even though hearing loss is one of the most common chronic conditions.

In a series of hearings I held as Chair of the Wisconsin State Senate's Aging Committee, our committee learned that hearing loss and other communicative disorders such as a speech impairment and related language deficiencies, affect over 500,000 people in Wisconsin alone. The invisible disability of hearing loss afflicts all age groups, and brings with it significant social and psychological problems as the hearing impaired withdraw from co-workers, neighbors, friends, and even family members.

This is not just as aging issue. It should be noted that while 60 percent of the hearing impaired are over 65, nearly 20 percent are children of school age, and neglected hearing problems can prevent a child's full intellectual and social development.

I very much hope today's hearing will lay the groundwork for additional work to address this significant health care issue, and that we can include it in the larger debate of health care reform.

Senator FEINGOLD. Thank you, Mr. Chairman. I was not here for all the comments, but I understand that Dr. Kessler and others have testified about the kinds of protections we should consider to protect consumers from abusive practices, and to insure that consumers are properly evaluated, assessed, and fitted by competent providers, and that's been helpful.

I'm also concerned about the problem of access. Only one in five people who could benefit from a hearing aid actually wear one, and as you know, neither Medicare nor private health insurance policies cover hearing tests or hearing aids, except, apparently, in rare instances.

My only question really is, what are your thoughts on improving access to the nearly 20 million citizens who could benefit from a hearing aid, and should hearing aids and tests be specifically covered as a benefit under the health care reform package that we're about to review.

I would start, at least, with Dr. Dixon, if possible.

Dr. DIXON. Well, I think a part of the problem is the negative connotation that hearing aids have. Historically, people have looked upon hearing aids as something to be avoided.

I think if we can have the same kind of attitude about hearing aids that we have about eyeglasses, more people would be willing to go and get fitted for hearing aids.

There again, we need education of the consumer.

The other problem about the imminent presentation of the health care reform package—we know that there are many, many needs in America that need to be addressed, and this is one of them. We also know that it's always a question of dollars.

Just as we'd look at other aspects such as long-term care in the health care reform package, we need to look at provisions of hearing aids for people who need them.

It might not be immediate, but it should be in there that somewhere down the road, we would know that this is something that we need to have addressed by our Federal Government.

Senator FEINGOLD. Is there any indication thus far that there will be any coverage provided in the plan or that that's been included in any way?

Dr. DIXON. Well, we haven't seen the plan yet, so we just don't know.

Senator FEINGOLD. Okay.

I thank you, Mr. Chairman.

Senator COHEN. Thank you very much.

Senator Grassley, do you have any questions?

STATEMENT OF SENATOR CHARLES GRASSLEY

Senator GRASSLEY. I'd like to place a statement in the record and ask one question.

I'm sorry I wasn't here to hear your testimony Dr. Dixon, but I did have a chance to read it ahead of time. Dr. Dixon, you made a point that many hearing aid sellers meet or exceed testing standards.

Now, my question is probably a balancing act—is there some way, in your judgment, to police those who are unscrupulous without placing stricter regulations on the system, and thus penalizing the honest seller?

Dr. DIXON. I doubt that we can do it without placing stricter regulations on the system.

I do not have the percentages of those who were not in conformance, but I think that just focusing on the problem—I think hearings such as the hearing that we are engaged in right now—focusing on the problem, and shedding the light on the ones who are unscrupulous will cause some changes in behavior, and of course, the prosecution of those who are in noncompliance, I think, will make a change.

Senator GRASSLEY. The standpoint of education and notoriety of abuse will bring some discipline. You don't feel, though, that that's enough—that there will still have to be some regulations, so that even the person who's very honest and forthright would still be negatively impacted?

Dr. DIXON. I think we have to have some regulation, but I don't think that those who are in conformance will be negatively impacted.

You know, just as we have all laws across the board to get the bad guys, the good guys are still the good guys, and I think they can publicize the fact that they are in compliance, and that will help their cases.

Senator GRASSLEY. Thank you.

[The prepared statement of Senator Grassley follows:]

PREPARED STATEMENT SENATOR CHARLES E. GRASSLEY

Mr. Chairman and Senator Cohen, I want to thank you for convening this morning's hearing. I was first exposed to this issue as a member of the Iowa State legis-

lature back in the early 1970's. In 1974, legislation was passed in Iowa to license hearing aid dealers. I recall that debate well and the divisiveness that surrounded the debate. Some of those same issues are once again before me.

Recent reports in the media have drawn attention to the potential problems in the hearing aid marketplace. So, I am eager to hear the witnesses before us who represent nearly all facets of this industry. However, I caution members of this Committee, and others, that although the media has drawn attention to some problems and abuses in the marketplace, it is our role to determine the extent of the problem and whether intervention is warranted.

One of the most important desires for an elderly person is to maintain their independence. For some, hearing loss threatens this independence. Hearing loss affects almost 23.5 million people, 60 percent of whom are over 65. Unfortunately, only 17 percent of the hearing impaired population wears a hearing aid. It is not entirely clear why more people do not use hearing aids. Cost may be a factor, dissatisfaction with an existing aid may be also a factor.

This hearing is an important first step in answering these and other questions. It is the first time in nearly 20 years that the Aging Committee has held a hearing on problems in the hearing aid marketplace. Not since Senator Percy chaired the Committee and held a hearing in 1976 has this issue been examined by the committee.

I concede that evidence appears to indicate that a number of problems and issues need to be examined. These issues involve the sale and advertisement of hearing aids, their regulation and who is the most appropriate provider of hearing aids. Some of the evidence is anecdotal but some is broad based.

There have been allegations of misleading advertisement and questionable sales practices within the industry. Recent reports also indicate some level of consumer dissatisfaction. The most recent report on consumer satisfaction has been conducted by AARP and will be released to today's hearing.

At the Federal level, the hearing aid industry is regulated by the FDA and the FTC. The States are primarily responsible for regulating the sale of hearing aids. State licensing boards set standards for competency, licensure, and practice. They are also responsible for investigating complaints and disciplining professionals. However, State regulations vary considerably. Evidence also indicates that State boards are not actively pursuing consumer complaints or disciplining professionals.

As I mentioned, this hearing is an important step in determining the status of the hearing aid market. We all share the common goal of providing high quality care to those who are hearing impaired. We must continue to guarantee access to quality care for the hearing impaired population. Access to health care is an important issue for me not only because I represent a rural State, but also a State with the highest percentage of seniors over 85. I am looking forward to this morning's testimony and determining what is the next course of action.

Senator COHEN. Thank you very much, Senator Grassley. And let me thank the panel for their testimony. They're very, very important. Thank you.

Our final panel will consist of Dr. Jerome Goldstein, who is the Executive Vice President of the American Academy of Otolaryngology.

He has served in this capacity since 1984. He has served as President of the American Society of Health and Neck Surgery, as well as the Director of the American Board of Otolaryngology.

Robin Holm currently serves as the Executive Director of the International Hearing Society. She represents the interests of the majority of the hearing aid dispensers in the United States.

She is a Board Certified Hearing Instrument Specialist and is a former President of the Society.

For nearly 20 years, Ms. Holm has been a co-owner and operator of a retail hearing aid establishment in Seattle, Washington.

Finally, Mr. Thomas O'Toole is President of the American Speech-Language-Hearing Association.

He has worked in the Montgomery County, Maryland public school system for over 30 years as Director of the Special Education

and Related Services, Director of Pupil Services, and Supervisor of Speech and Hearing Services.

Welcome, all of you—Mr. O'Toole, Dr. Goldstein, and Ms. Holm. Dr. Goldstein, would you like to begin?

I'd ask you if you could summarize your statements; the complete statement will be included in the record. I've been looking at that clock all morning, and the bells are bound to go off soon, and we'll be rushing off to a vote. But we'd like to have your testimony for the record.

STATEMENT OF JEROME GOLDSTEIN, M.D., EXECUTIVE VICE PRESIDENT, ACADEMY OF OTOLARYNGOLOGY

Dr. GOLDSTEIN. Okay. Thank you, Senator Cohen.

I am EVP of the world's largest organization of physician specialists dedicated to the diagnosis and treatment of patients with disorders of the ears, nose, throat, and related structures of the head and neck, and we appreciate this opportunity to present testimony.

Abuse does exist. Current regulations are not working. Many consumers, especially the elderly, are not informed and are not being medically evaluated before a hearing aid is provided, despite the 1977 FDA regulations. Part of this is related to Medicare's failure to provide coverage for any hearing aid-related medical services.

Mr. Chairman, hearing loss is a medical symptom, not a diagnosis. A hearing aid is not a treatment for a diseased ear, but an amplification device that helps many people with hearing loss overcome its limitations.

In some cases, hearing loss can be a symptom of a more serious problem, such as multiple sclerosis, AIDS, or an acoustic nerve tumor. That is why we feel it's vitally important that a diagnosis of the cause of the patient's hearing loss be made prior to a decision to recommend a hearing aid.

Ideally, consumers with hearing impairments who are seeking to purchase a hearing aid would be best served if they first consulted a physician specialized in treating ear disorders to rule out a treatable medical condition. This, clearly, is our first preference.

Hesitating aside, Senator Cohen, I detected some confusion this morning in the remarks of Senator Kohl, and even Dr. Kessler, on the distinction between a hearing evaluation and a medical evaluation, and perhaps in the questions, we can elaborate on that.

Although realistically, we know it's unlikely—given the current direction of health care reform—to have a physician see every patient, we are presenting today a possible compromise plan which we feel will expand access, hold down costs, and improve quality of care over the current state of affairs.

Our plan is as follows:

First, require all dispensers to assess the consumers' degree of hearing loss through a series of specific hearing tests.

Additionally, dispensers would be required to screen consumers for 10 specific "red flag" otolaryngologic conditions, such as dizziness or recurrent ear infections.

Should the consumer present any one of these "red flag" conditions, then the dispenser would be required to refer that individual

to a physician for medical clearance. There would be no waiver of this requirement.

Second, the "red flag" condition should be used for screening all purchasers of hearing aids, not just first time buyers.

Third, patients exhibiting none of the warning signals would still be required to sign a waiver statement. The formatting, size of the print, and text of this waiver statement should be nationally standardized, and the dispenser required to tell the patient that signing this waiver is not in his best health interest.

The statement must be presented to the consumer separate of any other paperwork requiring a signature, and civil and criminal Federal penalties should be established for noncompliance, including loss of licensure.

Finally, any patient receiving a hearing aid should be sent home from the dispenser with a warning card outlining conditions to be aware of regarding their hearing loss.

Should any of these conditions arise, the consumer would be instructed to seek medical care from their personal physician or a physician ear specialist.

We also strongly advocate banning mail order and door-to-door sales of hearing aids.

The approach I've just described is not the only, or even the final solution to solving abuse regarding this facet of the health care system, but it is a first step.

We encourage the FDA, Congress, primary care physicians, and nonphysician providers to join us in further evolving this concept of medical referral indicators for patients with hearing loss.

Such a coalition effort should surely produce quality guidelines that would expand access, reduce cost and, most importantly, protect the consumer.

Senator Cohen, you have asked also to discuss ways in which all physicians can be better educated about the diagnosis, treatment, and rehabilitation of hearing impaired individuals. We know all too well that many primary care physicians—pediatricians, family physicians, internists, and general practitioners—are not knowledgeable enough about ear disease to provide medical clearance. This is because many have not had to go through an otolaryngology rotation in either medical school or their residency training.

While some medical schools and residencies require rotations through otolaryngology departments, others do not; they're not available in all training institutions.

Our academy has been at the forefront of educating non-otolaryngologic physicians about hearing loss. We have available physician and patient education literature, we offer a slide lecture series, we present courses and sponsor exhibits at both the national and State level at the professional meetings of primary care physicians, and write articles for their professional journals.

We are exploring with the Association of American Medical Colleges ways to encourage mandatory rotations in otolaryngology for all primary care physicians.

I'd be happy to answer any questions you many have. Thank you.
[The prepared statement of Dr. Goldstein follows:]



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TESTIMONY OF THE AMERICAN ACADEMY OF OTOLARYNGOLOGY- HEAD AND NECK SURGERY BEFORE THE SENATE SPECIAL COMMITTEE ON AGING

HEARING AID DISPENSING AND MEDICAL CLEARANCE



PRESENTED BY
JEROME C. GOLDSTEIN, MD, FACS
EXECUTIVE VICE PRESIDENT

SEPTEMBER 15, 1993

1 The American Academy of Otolaryngology – Head and Neck Surgery (AAO-HNS) greatly appreciates this
2 opportunity to present testimony before the Senate Special Committee on Aging regarding the alleged
3 abuses in the hearing aid dispensing industry. I am Jerome C. Goldstein, MD, Executive Vice President of
4 the Academy. The Academy is the world's largest organization of physician specialists dedicated to the
5 diagnosis and treatment of patients with disorders of the ears, nose, throat, and related structures of the
6 head and neck. Otolaryngologists are sometimes referred to as ENT (Ear, Nose, and Throat) physicians;
7 many of our members specialize specifically in disorders of the ear.

8 I will focus my remarks on the need to strengthen the existing regulations governing the sale and dispensing
9 of hearing aids as it relates to medical clearance before a hearing aid is sold and offer recommendations
10 for change. Abuse of the adult waiver of the current requirement to obtain a medical evaluation by a
11 physician, preferably an otolaryngologist, prior to fitting and sale of a hearing aid is directly related to the
12 victimization of the public, often the elderly, by unscrupulous sales practices and/or the lack of expertise
13 on the part of a non-physician hearing aid dispenser who unknowingly overlooks serious problems requiring
14 medical referral and care. We will present a proposal that is responsive to the need for greater consumer
15 protection, is cost-effective, and uses the skills of all members of the hearing health care team.

16
17 **Background**

18 Current regulations, promulgated in 1977 by the Food and Drug Administration (FDA), governing the
19 conditions for sale of hearing aid devices require that a hearing aid dispenser not sell a hearing aid unless
20 the prospective user has presented a written statement signed by a licensed physician which states that the
21 patient's hearing loss has been medically evaluated and the patient may be considered a candidate for a
22 hearing aid. This medical evaluation must have taken place within the preceding six months. Adults, age
23 18 or older, may waive this requirement for a medical evaluation, but the hearing aid dispenser must:
24 "inform(s) the prospective user that the exercise of the waiver is not in the user's best health interest." The
25 prospective user must also sign a statement, as presented by the hearing aid dispenser which states: "I
26 have been advised by (hearing aid dispenser name) that the Food and Drug Administration has determined
27 that my best health interest would be served if I had a medical evaluation by a licensed physician (preferably
28 a physician who specializes in diseases of the ear) before purchasing a hearing aid. I do not wish to have
29 a medical evaluation before purchasing a hearing aid."

30 The statutory authority of the FDA to issue these regulations is tied to their general authority to regulate
31 medical devices. To our knowledge, there is no previous history of federal legislation specifically addressing
32 the protection of consumers in the sale of hearing aids.

33 **The Problems**

34 This waiver of the medical evaluation requirement, originally created to accommodate religious beliefs, such
35 as those of the Christian Scientists, has been grossly abused. Anecdotal evidence suggests that as many
36 as 85 percent of hearing aids sold to first time purchasers are done so through the use of the medical
37 waiver. This was clearly not the FDA's intentions. Consumers are rarely verbally informed by hearing aid
38 dispensers that it is in their best health interest to see a physician before obtaining a hearing aid.
39 Additionally, dispensers often include the waiver statement (in fine print) as part of a barrage of paperwork
40 which the prospective user is instructed to sign, further minimizing the importance of the waiver statement.

41 We believe that the majority of consumers are not fully informed; that hearing aids are sold to people who
42 do not need them; and that serious medical conditions are overlooked by non-physician providers
43 subsequently necessitating more extensive medical and or surgical treatment than would have been
44 necessary originally, adding additional cost and suffering to the patient and cost to the health care system.

1 States are responsible for the licensing of hearing aid dispensers and for enforcing the FDA's requirements
2 with respect to the medical evaluation and the waiver. However, requirements for licensure vary widely
3 across many states; some requiring as little as a high school diploma to apply for a license.

4 **Why the Need for a Medical Evaluation of Hearing Loss?**

5 Hearing loss is a medical symptom, not a diagnosis. A hearing aid is not a treatment for a diseased ear,
6 but an amplification device that helps many people with hearing loss overcome its limitations. A medical
7 examination allows the physician to assess the overall health of the patient, conduct a history and physical
8 and thoroughly examine the ears, nose and throat.

9 It is vitally important that a diagnosis of the cause of the patient's hearing loss be made prior to a decision
10 to recommend a hearing aid. Oftentimes, hearing loss can be medically and/or surgically managed,
11 replacing the need for a hearing aid or adding to its effectiveness. Hearing loss can be a symptom of a
12 more serious problem, such as multiple sclerosis, AIDS, or diabetes. Other times, systemic, metabolic, or
13 pharmacologic abnormalities or tumors may be the cause. These problems must not be overlooked and
14 delivering high quality medical care must be our goal.

15 **Health Care Reform and the Expanding Role of Allied Health Professionals**

16 We are all aware of the need to contain health care costs. Many health care reform proposals call for more
17 extensive use of allied health professionals to provide preliminary or routine health services and act as
18 gatekeepers to the system and to physicians to achieve cost containment. While we grapple with how to
19 contain health care costs, the simple solution is to take short cuts. Sometimes, the short cuts make sense.
20 Other times they are detrimental to patient care and more expensive in the long-run. We are concerned
21 about the arguments that the American Speech-Language Hearing Association (ASHA) and others are
22 making to eliminate altogether the current requirement to obtain a medical evaluation by a licensed physician
23 within the preceding six months prior to the first purchasing of a hearing aid. ASHA is seeking to overturn
24 the regulation by arguing that "it is more cost-effective for an audiologist to evaluate the type and degree
25 of hearing loss, determine candidacy for amplification, and refer, if needed, for medical management."
26 (ASHA Dear Colleague letter, May 10, 1993)

27 Although the Academy is concerned with the costs of health care, we believe cost should not be the driving
28 factor for delivering patient care, particularly if it means patient care will suffer. Failing to correlate disease,
29 overlooking tumors, and over-prescribing amplification are not goals that any of us should entertain. We
30 are concerned that without the medical evaluation requirement, more people will start falling into the cracks
31 of the health care system. Delivering high quality medicine should be everyone's bottom line.

32 **Recommendations for A Change in Federal Policy**

33 The Academy has created an alternate proposal to the current policy which will better serve the public by
34 improving quality of care, and direct scarce health care resources where they will do the most good. We
35 hope that our plan will gain the support of the FDA and all other interested parties, including audiologists,
36 who we urge to join us in support of this plan.

37 The basic provisions of our proposal would require federal regulations to be revised as described below.
38 The following recommended changes pertain to adults only. All children under the age of 18 must still
39 obtain a medical evaluation by a physician, preferably an otolaryngologist, before a hearing aid is offered.
40 Children would not be permitted to waive this requirement as current regulations dictate.

- 1 A. Require a hearing evaluation to be conducted by a hearing aid dispenser such as an audiologist or
2 other hearing professional licensed by the state prior to the dispensing of the hearing aid. There
3 would be no waiver of this requirement. The hearing evaluation would include the following
4 diagnostic tests: air, and bone conduction thresholds, speech understanding, most comfortable
5 loudness (MCL) and uncomfortable loudness (UCL) levels. The hearing evaluation would also
6 include screening for any red flag otologic conditions as specified below. Referral to a physician,
7 preferably an otolaryngologist, would be mandatory if any of the conditions existed. Attached to
8 this testimony is a suggested questionnaire that the hearing aid dispenser could use to aid in this
9 process.
- 10 B. Require a medical evaluation by a physician, preferably one trained in diseases of the ear
11 (otolaryngologist). A waiver of this requirement would be allowed only if the patient did not exhibit
12 any of the following red flag otologic conditions, also referred to as medical referral criteria:
- 13 1. Visible congenital or traumatic deformity of the ear.
14 2. Hearing loss with positive history of tuberculosis, syphilis, HIV, Meniere's disease,
15 autoimmune disorder, otosclerosis, Von Recklinghausen's neurofibromatosis, or Paget's
16 disease of bone.
17 3. History of active drainage or bleeding from an ear within previous six months.
18 4. Sudden or rapidly progressive hearing loss within previous six months.
19 5. History of sudden or rapidly progressive hearing loss or a sudden or recent onset within
20 previous 90 days.
21 6. Unilateral or asymmetric hearing loss.
22 7. Acute or chronic dizziness.
23 8. Audiometric air-bone gap equal to or greater than 15 decibels at 500 hertz (Hz), 1000Hz
24 and 2000 Hz.
25 9. Visible evidence of cerumen accumulation or foreign body in the ear canal.
26 10. Bilateral hearing loss of greater than 90 decibels.
- 27 We do not want to create the impression that a medical evaluation is needed only for the conditions
28 enumerated above. Indications for medical referral should not be limited to these conditions, but
29 they do cover the overwhelming majority of conditions that would be problematic.
- 30 C. In the event that an adult hearing aid purchaser does not exhibit any of the red flag otologic
31 conditions, a waiver of the requirement to obtain a medical evaluation would be allowed. However,
32 the consumer would still be required to be informed by the hearing aid dispenser both verbally and
33 in writing that it is still in their best interest to see a physician (preferably an otolaryngologist) for
34 a medical clearance prior to the fitting of the device and sign an appropriately written and presented
35 waiver statement. The formatting, size of the print, and the text of this waiver statement should be
36 nationally standardized for maximum understanding. The waiver statement should stand alone from
37 any other paperwork given to the consumer in the purchase of the hearing device.

1 D. Require federal and encourage state penalties for violation of the regulations, such as civil, criminal,
2 and loss of licensure. Professional sanction should also be considered. Given that there are not
3 enough funds for real enforcement, as the present situation dictates, these penalties are suggested*
4 as a deterrence for non-compliance.

5 E. These requirements would not just apply to first time purchasers. If a patient is purchasing a
6 second or third (or more) hearing aid, the hearing aid dispenser would still be required to evaluate
7 the patient for any of the red flag otologic symptoms; if any were present a medical evaluation
8 would be required without the option of waiving. The battery of diagnostic hearing tests required
9 for first time purchasers would not necessarily be required to the same extent for second and third
10 (etc) time purchasers.

11 F. After the fitting of a hearing aid, all patients would be sent home with a warning card that says:

12 Contact your personal physician or a physician ear specialist (Otolaryngologist-Head and Neck
13 Surgeon or Otolologist) for :

- 14 1. Ear pain, especially if associated with acute or chronic throat pain, fever, or ear tenderness.
- 15 2. Sudden or rapidly progressive loss of hearing, even with recovery.
- 16 3. Dizziness.
- 17 4. Persistent blocked feeling in an ear.
- 18 5. Hearing loss worse on one side.
- 19 6. Hearing loss after air travel, a fall, or a blow to the head.
- 20 7. Hollow or open feeling in an ear, especially if it is abolished by forceful sniffing.
- 21 8. Bleeding or drainage from an ear.

23 The identified goals of health care reform are to expand access, hold down costs, and improve or at least
24 maintain quality. We believe our proposal promotes all three goals. Many patients will not be required to
25 see a physician, saving time and expense. Those who did need to see a physician would be preferably
26 directed to an otolaryngologist who would be able to provide the most cost-effective quality care. The role
27 of audiologists and other allied health professionals would be expanded and specific guidelines for physician
28 referral are provided. States would have concrete grounds on which to prosecute abuses of the regulations.
29 Physicians, audiologists, and hearing aid dispensers would be encouraged to work together for cost
30 containment, access, and quality care.

31 Mr. Chairman and Senator Cohen, you have asked me to also discuss ways in which all physicians can be
32 better educated about diagnosis, treatment, and rehabilitation of hearing impaired individuals. We know all
33 too well that many primary care physicians (pediatricians, family physicians, internists, and general
34 practitioners) are not knowledgeable enough about ear disease to provide medical clearance. This is
35 because many have not had to go through an otolaryngology rotation in either medical school or in their
36 residency training. While some medical schools and residencies require rotations through otolaryngology
37 departments, others do not – most likely because they are not available in those particular institutions. The

1 AAO-HNS has been at the forefront of educating non-otolaryngic physicians about hearing loss. We have
 2 available physician and patient education literature and offer a slide lecture series. We present courses and
 3 sponsor exhibits at both the national and state level at the professional meetings of primary care physicians
 4 and write articles for their professional journals. We anticipate exploring with the Association of American
 5 Medical Colleges (AAMC) ways to encourage mandatory rotations in otology for all primary care physicians.

6 The American Academy of Otolaryngology – Head and Neck Surgery thanks you again for this opportunity
 7 to testify. We look forward to working with you toward improving the hearing health of all Americans. I'd
 8 be happy to answer any questions that you may have.

9 Attachment.
 10

American Academy of Otolaryngology – Head and Neck Surgery

Suggested Questionnaire for Use by Hearing Aid Dispensers in Identifying Need for Medical Referral

Suggested questionnaire Answer each question

Yes	No	Not Sure
-----	----	-------------

Do you have any blood relatives with hearing loss before age 40?

Do you have any hearing loss that occurred suddenly, such as instantaneously or over hours or days, or months, as opposed to years?

Have you had any dizziness?

Have you had any hearing loss associated with air travel, a blow to the head?

Do you have any birth defect of the head, neck, brain, or ear?

Have you had any ear surgery?

Have you had any foul-smelling drainage from the ear?

Have you been told you have an ear infection or an ear cyst?

Have you been told you have perforated or ruptured ear drum or a hole in the ear drum?

Do you have or have you ever had any of the following:

- tuberculosis

- syphilis

- HIV infection or AIDS

- Meniere's disease

- autoimmune disorder

- otosclerosis

- Paget's disease of the bone

- Numbness or paralysis of the face

Do you or anyone in your family have Neurofibromatosis (Von Recklinghausen's disease)

* A hearing aid should not be considered treatment

Senator COHEN. Thank you very much, Dr. Goldstein.
Dr. O'Toole.

**STATEMENT OF DR. THOMAS O'TOOLE, PRESIDENT,
AMERICAN SPEECH-LANGUAGE-HEARING ASSOCIATION**

Mr. O'TOOLE. Mr. Chairman, I'm Tom O'Toole, President of the American Speech-Language-Hearing Association, ASHA.

ASHA appreciates the opportunity to submit testimony to the Senate Special Committee on Aging.

ASHA's comments are made with the support of related audiology organizations, including the American Academy of Audiology, the Academy of Dispensing Audiologists, the Academy of Rehabilitative Audiology, and the Educational Audiology Association.

ASHA is the national professional, scientific, and credentialing organization for 75,000 audiologists and speech-language pathologists. The more than 11,000 audiologists who hold ASHA's certificate of clinical competency are hearing care professionals with a masters or doctoral degree, who have met stringent academic and clinical practicum requirements, passed a national examination, completed a supervised internship experience, and agreed to abide by ASHA's code of ethics.

Audiologists specialize in preventing, identifying, and assessing hearing disorders, as well as providing treatment that includes the selection, fitting, and dispensing of hearing aids and assistive devices.

Audiologists provide audiology rehabilitation services for children and adults with hearing loss.

Audiologic rehabilitation refers to service procedures for facilitating communication in individuals with hearing loss.

I thank the Chairman for scheduling this important hearing, and I also want to acknowledge the work of the ranking Republican, Senator Cohen.

It is my understanding that Senator Cohen has long been interested in this subject, and was instrumental in planning today's hearing.

We have particular concerns about quality hearing care service delivery for persons over 65 years of age. The issue of proper hearing care for all Americans is important, and for older persons it is crucial.

The incident rate of hearing loss increases dramatically for older persons. Hearing aids and audiology rehabilitation hold promise for diminishing the isolating effects of hearing loss so that the full spectrum of life's activities can be enjoyed.

Our testimony focuses on—one, the Food and Drug Administration regulations; two, State regulation of audiologists; and three, hearing aids and consumer education.

We applaud FDA's plan to revise and update its 1977 regulations to reflect changes in the hearing care system and to insure greater consumer protection.

We recognize that only a small number of individuals with severe and irreversible hearing loss can be helped by current medical or surgical intervention.

We propose that new regulations ensure that individuals who are evaluated for hearing aid candidacy receive comprehensive diag-

nostic audiologic assessment to determine the degree and type of hearing loss, and ensure that appropriate medical referrals are made; and that individuals receive a complete battery of measures to gauge the appropriate selection and fitting of a hearing aid and/or an assistive listening device; and three, that the critical audiologic rehabilitation and related follow-up care are provided.

Audiologists have the knowledge and skills necessary to assess the type and degree of hearing loss, and to refer for medical treatment. Training and evaluation, fitting, and dispensing of hearing aids and other assistive devices is a regular part of the curriculum for graduate education in audiology.

We welcome efforts by FDA to ensure that advertisements for hearing aids contain accurate information. Positive and truthful advertising will promote hearing aid use by those consumers who can benefit from professionally and properly fitted hearing aids.

ASHA strongly believes that effective State regulation for hearing aid dispensing is in the best interest of persons with hearing loss, particularly older persons who are less likely to recognize bad buying experiences and less likely to complain when they do recognize them.

Currently, 41 States require audiologists to be licensed, and one State requires audiologists to be registered.

ASHA actively promotes licensure legislation in States without such a policy.

Without exception, licensure laws for audiologists contain high standards for formal academic education, and supervised practicum experience.

All States require applicants to show evidence of meeting requirements based on those necessary for the ASHA certificate of clinical competence, namely a masters or doctoral degree in audiology, among other requirements.

State regulation of the profession of audiology is characterized by strong consumer involvement. Eighty-seven percent of the States with audiology licensure boards have at least one consumer member, and often two public members who have full voting rights.

Even with strong consumer participation, State professional regulation is a less-than-perfect system.

Licensure laws need periodic revision to reflect current advances in technology, minimum standards of appropriate practice, and clear delineation of unfair and deceptive practices.

Licensing agencies need stronger disciplinary powers and they must have greater resources for enforcement and consumer education.

Hearing aids can help millions of people with hearing loss who do not currently use them.

Potential hearing aid users need to become more educated consumers, and they need to know that hearing aids can benefit many different types of hearing loss.

They need to know prior to purchase, what hearing aids can and cannot do. They need to learn about hearing care providers and the range of service and products they offer. They need to understand the value of audiologic rehabilitation, and obtain follow-up care that includes amplification orientation, lip reading, counseling,

communication strategies, and information on related technology and support.

Thank you, Mr. Chairman, for giving ASHA the opportunity to represent America's audiologists at today's hearing. Our written testimony contains specific recommendations for the Committee's consideration.

We are eager to work with consumers, policymakers, service providers, and manufacturers to improve the current hearing care system, and to better provide care for people of all ages with hearing loss.

[The prepared statement of Mr. O'Toole follows:]



AMERICAN
SPEECH-LANGUAGE-
HEARING
ASSOCIATION

Submitted by:
Thomas J. O'Toole, EdD
President,
American Speech-Language-
Hearing Association
September 15, 1993

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Introduction

The American Speech-Language-Hearing Association (ASHA) appreciates the opportunity to submit the following statement to the Senate Special Committee on Aging. We are pleased that the statement will be included in the record of these hearings along with a number of documents we have included for your information: official policy statements of the audiology associations, pertinent research, and guidance on hearing services for consumers. ASHA's comments are made with the support of related audiology organizations that include the American Academy of Audiology, the Academy of Dispensing Audiologists, the Academy of Rehabilitative Audiology, and the Educational Audiology Association.

ASHA is the national professional, scientific, and credentialing organization for 75,000 audiologists and speech-language pathologists. The more than 11,000 audiologists who hold ASHA's Certificate of Clinical Competence in Audiology are hearing care professionals with a master's or doctoral degree who have met stringent academic and clinical practicum requirements, passed a national examination, completed a supervised internship experience, and agreed to abide by ASHA's Code of Ethics, which incorporates the highest ethical principles. Audiologists specialize in preventing, identifying, and assessing hearing disorders, as well as providing treatment that includes the selection, fitting, and dispensing of hearing aids, assistive listening, and alerting devices. Audiologists provide aural rehabilitation services for children and adults with hearing loss. Aural rehabilitation refers to services and procedures for facilitating adequate receptive and expressive communication in individuals with hearing loss.

I thank the Chairman for scheduling this important hearing. I also want to acknowledge the work of the ranking Republican, Senator Cohen. It is my understanding that Senator Cohen has long been interested in this subject and was instrumental in planning today's hearing.

We are pleased that the Senate Special Committee on Aging has chosen to hold these hearings because we have particular concerns about quality hearing care service delivery for persons over 65 years of age. The issue of proper hearing care for all Americans is important; for older persons, it is crucial. The incidence rate of hearing loss increases dramatically for older persons. Hearing aids and audiology rehabilitation hold promise for diminishing the isolating effects of hearing loss so that the full spectrum of life's activities can be enjoyed. This population has unique needs, however, with a high occurrence of vision, motor, and cognitive deficits in addition to hearing loss. These factors must be recognized when assessing hearing and recommending treatment and amplification devices for people over 65 years of age.

Our testimony today will focus on three major areas of concern to the Committee: (1) the Food and Drug Administration regulations related to hearing aid devices, (2) state regulation of audiologists involved in dispensing hearing aids, and (3) hearing aids and consumer education.

1977 Food and Drug Administration Regulations:

Hearing Aid Devices - Professional and Patient Labeling and Conditions for Sale

In 1977, the Food and Drug Administration (FDA) promulgated regulations for the conditions for hearing aid sales to address allegations of abuse in hearing aid sales practices. Current FDA regulations require physician evaluation to ensure that the consumer receives appropriate medical treatment when indicated. The requirements of these regulations were well-intended as a means of protecting consumers and enhancing labelling information. However, the overwhelming majority of persons with permanent irreversible hearing loss cannot benefit from either medical or surgical intervention.

The Food and Drug Administration is taking important steps to revise and update the 1977 regulations and we applaud this needed action. It is critical that new regulations ensure that a) individuals who are evaluated for hearing aid candidacy receive comprehensive diagnostic audiology assessment to determine the degree and type of hearing loss and ensure that appropriate medical referrals are made when needed, b) individuals receive a complete battery of measures to gauge the appropriate selection and fitting of a hearing aid and/or assistive listening device, and c) the critical audiology rehabilitation and related follow up care are provided.

For appropriate delivery of core diagnostic and treatment services, consumers must receive care from qualified professionals knowledgeable about technology, about its applications to an ear that has sustained permanent damage, and about the effects of hearing loss on communication and quality of life. Audiologists have the knowledge and skills to assess the type and degree of hearing loss and refer for medical treatment. Training in the evaluation, fitting, and dispensing of hearing aids and other assistive devices is a regular part of the curriculum for graduate education in audiology. In addition, ASHA has adopted preferred practice patterns and policies on best practice for diagnostic audiologic testing, hearing aid selection, audologic rehabilitation, and product dispensing that reflect quality care for all persons receiving services from a certified audiologist. We anticipate that, in revising the 1977 regulations related to hearing aid devices, the FDA will recognize the important role the audiologist plays in ensuring that consumers receive appropriate and comprehensive services.

Also, we welcome efforts by the FDA to ensure that advertisements for hearing aids contain accurate information. Audiologists share the FDA's concern about the effects of advertising on the public's view of hearing aids as an estimated three-fourths of the consumers who need and can benefit from technological advances in hearing aid design do not utilize available services and products. We hope that investigations by the FDA, this committee, and other agencies and organizations will lead to positive and truthful advertising and promotion to encourage hearing aid use by consumers who can benefit from professionally and properly fit hearing aids.

State Regulation of Audiologists

ASHA strongly believes that appropriate and effective state regulation for the dispensing of hearing aids is in the best interest of persons with hearing loss, and particularly older persons who are less likely to recognize bad buying experiences and less likely to complain when they do recognize them. Currently, 41 states require audiologists to be licensed, and one state requires audiologists to be registered. ASHA actively promotes licensure legislation in states without such a policy. Additionally, ASHA encourages the revision of existing laws so that they reflect the contemporary practice of audiology and technological advances in providing comprehensive hearing care services and products.

Without exception, licensure laws for audiologists contain high standards for formal academic education and supervised practicum experiences. All states require applicants to show evidence of meeting requirements based on those necessary for the ASHA Certificate of Clinical Competence in Audiology—namely, a master's or doctoral degree in audiology; supervised clinical practicum; passing a standardized, written national examination in audiology; and a supervised postgraduate professional experience. The majority of states, however, also require licensed audiologists to obtain a hearing aid dealer's license to dispense hearing aids. This requirement to hold two licenses and pay two fees is in effect even though the academic and practicum requirements for audiologists far exceed those for hearing aid dealers. This dual requirement creates an unnecessary regulatory burden. However, in 13 states this burden has been removed from audiologists and they are permitted to dispense hearing aids under their audiology licensure laws.

State regulation of the profession of audiology is characterized by strong consumer involvement. Eighty-seven percent of the states with audiology licensure boards have at least one consumer member and, often, two public members, who have full voting rights. Arkansas and Ohio require that one of the two consumer members be individuals who are older adults. Maryland and Wisconsin require one of the two consumer members to be an individual with a hearing loss.

ASHA acknowledges that, even with strong consumer participation, state professional regulation is a less-than-perfect system. Licensure laws need to be updated to reflect current practice and technology and to include minimum standards of appropriate practice and a clear delineation of unfair and deceptive acts and practices. Licensing agencies need greater and more varied disciplinary powers and more fiscal and personnel resources to assist them in their enforcement efforts. And, finally, all state agencies regulating the provision of services and sale of products should take an active role in educating consumers on how to make complaints and for what reasons.

Hearing Aids and Consumer Education

Of the estimated 25.8 million Americans who are hard of hearing or deaf, approximately 5.8 million own a hearing aid (Hearing Industries Association-MarkeTrak III; 1991). Those remaining people who could enhance their communication abilities through use of amplification either fail to seek professional help or are sometimes inappropriately advised by primary care providers that hearing aids are not that useful. Many of these

people are 65 years of age or older. Our consumer focus group research has shown that there are many reasons for people not using hearing aids. The typical reasons include misinformation that their type of hearing loss is not severe enough or cannot be helped by amplification; unrealistic expectations of the benefits of hearing aids; the cost of hearing aids; and, the perceived stigma associated with hearing aid use. Surveys have indicated that thirty percent of purchasers of hearing aids stop using them because they do not know how to properly care for and maintain the devices or use them effectively.

Without a hearing aid, communication in business, social, and family situations becomes more difficult. People with hearing loss may perform less capably in these situations; withdraw from participation; and feel isolated from people and activities that once provided personal satisfaction, fulfillment, and enjoyment.

We believe that hearing aids must be provided as part of a comprehensive program of audiology rehabilitation. Hearing aids can help millions of people with hearing loss who do not use them. But, these potential users need to become more educated consumers. They need to know that hearing aids can benefit many different types of hearing loss. They need to know what hearing aids can and cannot do prior to their purchase. They need to learn about hearing care providers and the range of services and products they offer. They need to understand the value of audiology rehabilitation and follow-up care after buying their hearing aids.

It is not surprising that some hearing aid purchasers report dissatisfaction because they expect hearing aids to eliminate completely background noise in all listening situations. When reality does not meet expectations, the consumer becomes dissatisfied. While further advances in technology are needed to assist in clarifying speech signals in the presence of background noise, current technology affords enhanced listening capability for the majority of children and adults needing amplification when selection and fitting of the hearing aid is provided by a qualified professional. It is important that an appropriate hearing aid be selected that compensates for the individual's specific hearing loss and meets his or her specific listening needs. For older persons, deficits in vision, manual dexterity, and cognition must be considered for determining appropriate treatment strategies.

Audiologists believe that the vast majority of persons with hearing loss can benefit from the technological advances that have derived from the hearing aid industry's research and development efforts. Several studies that have measured perceived disability before

and after hearing aid fitting indicate that adults with hearing loss score less "disabled" following appropriate fitting of a hearing aid and counseling as to proper use.

A comprehensive program of treatment will promote an ongoing relationship between the hearing care provider and the consumer. Essential follow up care will encompass a variety of services including amplification orientation, lipreading, counseling on the effects of hearing loss, communication strategies, and information on related technology and support groups.

Recommendations

The following is a list of specific recommendations we respectfully make to the committee for your consideration and further action:

- All state hearing aid regulatory bodies should have consumer members with full voting rights;
- All state hearing aid regulatory bodies should have sufficient resources to effectively monitor compliance with hearing aid laws and regulations, identify non-compliance, issue corrective actions, and enforce appropriate sanctions;
- All states should license audiologists and permit dispensing of hearing aids within the provisions of the audiology license;
- State audiology licenses should reflect contemporary practices and technology advances in comprehensive hearing care services and products and require the highest standard for knowledge, education, and skills;
- Federal regulations should recognize audiologists as autonomous providers of hearing care services, hearing aids, and related services;
- Federal agencies should have sufficient resources to perform compliance activities regarding regulatory requirements;
- Consumers with hearing loss should be advised to use audiologist's services to -
 - determine the type and degree of any hearing loss;
 - rule out the need for referral for medical intervention;
 - learn about the appropriateness of candidacy for hearing aid fitting, benefits and limitations of hearing aids, and the application of other assistive listening devices;
 - receive a hearing aid evaluation from an ASHA-certified, and where applicable, state-licensed audiologist;
 - receive a trial period of hearing aid use after purchase; and
 - obtain appropriate follow-up care and audiologic rehabilitation.

Hearing loss is the disability that can be and is often ignored until the effects on work and social life prove devastating. It is important that we convey a message that is straightforward about the value that hearing aids bring to maintaining functional independence and enhancing the quality of life for persons with a hearing loss.

Again, thank you Mr. Chairman, for giving ASHA the opportunity to represent America's audiologists at today's hearing. We hope we have contributed to a better understanding of the hearing care system, and we are eager to work with the Committee to improve the system for consumers of all ages with hearing loss. The hearing care system can be complex and confusing. We strongly believe, however, that by working together, consumers, policy makers, service providers, and manufacturers can improve the hearing care system in America.

Senator COHEN. Thank you very much, Mr. O'Toole.

And now, Ms. Robin Holm, let me once again apologize for my initial introduction. It brings to mind the admonition that one should never walk with his or her head down, nor should one ever introduce a witness with his or her head down. So Ms. Robin Holm, please, we welcome you.

**STATEMENT OF MS. ROBIN HOLM, EXECUTIVE DIRECTOR,
INTERNATIONAL HEARING SOCIETY**

Ms. HOLM. Thank you, Senator, and your apology certainly is not necessary.

My name is Robin Holm, and I am the Executive Director of the International Hearing Society.

As a former hearing instrument specialist for over 20 years, I am pleased to present this testimony on behalf of IHS.

In the interest of time, I would like to summarize a longer statement that I submit now for the hearing record.

IHS was founded in 1951, and represents the majority of hearing aid specialists in the United States.

IHS members are the leading providers of hearing testing, fitting, repair, and counseling services. Our members include licensed hearing aid dispensers, many of whom are nationally certified by the National Board for Certification in Hearing Instrument Sciences, and also dispensing audiologists.

We conduct programs of competency, accreditation, specialty level certification, education, and training. We provide a toll-free hearing aid help line to give guidance to consumers and mediate consumer problems.

The issues raised today are not new. They have been examined in various Congressional and regulatory hearings since 1962.

After thorough investigations, concerns about marketing practices have proven to be anecdotal in nature, and not substantiated by consumer dissatisfaction data.

Indeed, despite the anecdotal stories that you have heard today, the vast majority of hearing aid dispensers are honest, competent, and dedicated to serving their customers.

AARP's own report found that 79 percent of their respondents were satisfied with their providers.

In addition, allegations that the elderly are more complacent and less inclined to complain, I personally find to be insulting, and I find them to be without foundation.

IHS members are proud of their record. For more than 15 consecutive years, complaints about hearing aids or hearing aid providers have been tabulated at less than one-half of 1 percent of the total number of sales.

Nevertheless, we are concerned about even one complaint.

Can the system be improved? We think so.

In fact, today we will propose six substantial initiatives to strengthen the existing hearing aid delivery system.

The Committee already knows that over 26 million Americans suffer from hearing impairment, yet only a fraction use hearing aids.

We must not create additional unnecessary barriers which will dissuade hearing impaired Americans from seeking assistance.

Nearly 95 percent of all hearing loss cannot be corrected, medically or surgically. For those people, their only answer—their only hope—is hearing instrumentation, assistive listening devices, and/or some other form of aural rehabilitation.

According to the Food and Drug Administration, a hearing aid is neither a dangerous nor a prescriptive device. It is, however, one of the most heavily regulated devices, and remains today the only device that FDA has chosen to classify under its broader powers as a restricted medical device.

Also, we know that 46 States have licensing laws regulating hearing aid providers. IHS supports the aggressive enforcement of these laws.

We believe, for the most part, they are good laws, but we remind you that an entire industry should not, can not, and must not be tainted because certain individuals will violate any given law.

Hearing specialists properly refer possible medical conditions to physicians. The debate about the FDA waiver, we believe, misses the point.

The existence of the waiver in a patient's file demonstrates compliance with the FDA regulation, and not a violation of those rules.

Most potential medical conditions are obvious from the patient history, from observation, or from basic testing procedures.

Both AAO and the FDA have found that our members and other qualified providers are fully capable of identifying the "red flags" for medical evaluation, and for making appropriate medical referral.

IHS is pleased today to recommend the following initiatives, which we believe will improve the existing regulatory scheme:

First, we concur with Dr. Kessler's comments, and we would also recommend that a standard battery of hearing evaluation test protocols be developed.

We also believe that we must develop a uniform patient history form.

Number three, we would recommend the development of a comprehensive model hearing aid dispensing licensing statute.

Four, we would recommend that we require mandatory medical referral for all patients presenting any of the eight "red flags."

Number five, we recommend that we clarify regulatory disclosures currently in existence.

And number six, we recommend that we evaluate how we can assure compliance with mail order hearing aid sales, or better yet, eliminate them entirely.

This package of proactive measures advanced by IHS will preserve the existing hearing health care team, provide far greater levels of consumer protection, be cost effective, and establish a much-needed standardized testing protocol from which each and every American experiencing hearing loss will benefit. Thank you.

[The prepared statement of Ms. Holm follows:]



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WRITTEN TESTIMONY OF THE
INTERNATIONAL HEARING SOCIETY
BEFORE
SPECIAL COMMITTEE ON AGING
UNITED STATES SENATE
SEPTEMBER 15, 1993

We appreciate the opportunity to submit these comments in conjunction with your review of the hearing aid industry. Upon review and evaluation of our industry, the Committee should conclude that, while improvements may be desirable and achievable, hearing aids are valuable and effective devices which provide benefit and satisfaction to millions of Americans. The Committee also will conclude that hearing instrument specialists are critical and qualified members of the hearing health team. In fact, there is widespread agreement that the 20 million hearing impaired persons who do not currently wear hearing aids could benefit from their use.

The International Hearing Society ("IHS") represents the vast majority of traditional hearing aid dispensers in the United States. Our members include licensed hearing aid dispensers, hearing instrument specialists certified by the National Board for Certification in Hearing Instrument Sciences ("NBC-HIS") and many dispensing audiologists certified by the American Speech-Language-Hearing Association ("ASHA").

IHS, and its predecessor organizations, have represented hearing aid dispensers for over 40 years. IHS members are small business men and women strategically located and accessible to the hearing impaired public throughout the United States. They are located in rural areas, small towns and major metropolitan centers. A large number of IHS members are second and third generation hearing instrument specialists, many with degrees in audiology.

IHS conducts programs in competency accreditation, education and training, and promotes specialty level certification for its members. IHS has been an active supporter of consumer advocacy for hard of hearing individuals. For example, we sponsor and promote a toll-free Hearing Aid Helpline which provides guidance to the hearing impaired, mediates consumer complaints and assists callers in locating qualified providers of hearing services.

The Committee has requested that IHS respond to several issues, which we are pleased to do. In conjunction with our response, we have included some background information on the industry that the Committee may find useful.

The issues addressed by the Committee are not new. Since at least 1962, at the impetus of advocates for the elderly, the Congress has evaluated allegations of abusive hearing aid sales practices in at least five sets of public hearings. These allegations were generally dismissed as anecdotal and not substantiated by consumer dissatisfaction data or by complaints to state consumer protection authorities.

As recent as 1985, the Federal Trade Commission terminated its extensive formal rulemaking proceedings after ten years of field hearings, studies and consumer surveys, finding that further regulation was not necessary or appropriate. In 1977, the FDA classified hearing aids as the only restricted medical device in its history and issued regulations governing, not its pre-market evaluation for safety and efficacy, but its labeling, promotion and sale.

BACKGROUND

Hearing impairment is a major national health problem. There are over 26 million Americans who suffer from loss of hearing. Only a fraction of these Americans (approximately 5,000,000) utilize hearing aids. Unfortunately, too many Americans subscribe to the myth and misperception that hearing loss is a stigma of aging, or more precisely of infirmity, which must be ignored or disguised. The most serious problem faced by the public is ignorance; ignorance about hearing loss, ignorance about the benefits of hearing aids, and ignorance about the services and skills of hearing aid providers. IHS hopes that much of the confusion and the misperception about the hearing aid industry will be alleviated by these hearings.

The hearing aid is unique among medical devices and most consumer health products. In its most recent rulemaking in 1977, the FDA specifically found that hearing aids were not harmful devices. A hearing aid is neither a dangerous device nor a prescriptive product. It is, however, already one of the most heavily regulated devices in the marketplace. Yet, the number of persons who will in fact require medical or surgical treatment is small in comparison to the number of hearing impaired individuals who may benefit from amplification, according to the FDA. Among adults, it is estimated by ASHA ("How To Buy A Hearing Aid") that only 5-10% of individuals with hearing problems have conditions which are medically or surgically treatable. There is, regrettably, no medical or surgical treatment for the predominant cause of hearing loss (*i.e.*, sensorineural) among senior citizens resulting from the aging process.

Hearing aids have advanced from "hearing trumpets" in the early 19th Century, to vacuum tube aids early in the 20th Century and to transistor aids in the 1950's. By the 1960's, a new generation of transistors offered a breakthrough in the size of hearing aids. As a result of research during the last decade, hearing aids now contain transistors the size of a pinhead and are more powerful than any of their predecessors. Through integrated microchip circuitry, these tiny transistors can focus on specific frequencies and the proximity of sound to better meet the needs of the consumer.

Hearing aids are commonly referred to as "in-the-canal" ("ITC"), "in-the-ear" ("ITE") or "behind-the-ear" ("BTE") instruments, depending on where they are worn. State-of-the-art technology, including active filters, directional microphones, and programmable circuitry, help wearers function better in a variety of listening situations.

During the past five years, there has been an even more rapid technological evolution of hearing aids. Engineers and scientists are designing components to deliver sound to the ear that replaces lost or distorted cues which contribute to the understanding of speech. The new generation of devices will change microphone direction, amplifier-type and fidelity of sound to reduce background noise and focus on speech.

Advances in digital technology have allowed for the incorporation of new performance features into analog hearing aids. Many manufacturers are now introducing hybrid analog/digital devices which include low voltage integrated circuit technology. Currently, digital processing allows the wearer to program the hearing aid easily for different performance characteristics depending on the listening environment. Digital technology is also useful in limiting acoustic feedback and in noise-reduction. Improvements in hearing aid sound quality continue to be made with the dramatic technological advancements in analog electronics and digital signal processing.

Hearing aid dispensers practice primarily through small businesses. There are 9,000 dispensers in the United States of which approximately 5,300 are traditional hearing aid dispensers, 2,200 dispensing audiologists in private practice and 2,400 dispensing audiologists in clinics and doctors' offices.

A recent industry survey indicates that the average dispenser purchases hearing aids from five to seven manufacturers. The same surveys indicate that most customers (approximately 60%) are over 65 years of age. Repeat purchasers and referrals, including from physicians, represent almost 70% of all sales. The ITE aids constitute 80% of sales by all categories of dispensers. Pricing of hearing aids is very competitive. The average price of an ITE aid is \$670. When sold by hearing instrument specialists, this price includes testing and fitting fees in 90% of sales. Testing and fitting fees are included in the price of the instrument in 55% of the sales by dispensing audiologists in private practice. Dispensing audiologists in clinics and doctors' offices include testing and fitting fees in only 24.5% of sales. Hearing Instruments, Vol. 44, No. 6. (1993).

1. THE EXISTING FDA REGULATIONS

Hearing aids are the only Class I medical device whose use is restricted by the FDA. The FDA promulgated its regulations, entitled "Professional and Patient Labeling and Conditions For Sale for Hearing Aid Devices" (42 Fed. Reg. 9386, et. seq.) ("Regulations"), on February 15, 1977. The Regulations provide, among other requirements, that prospective purchasers must be

advised that good hearing health care requires that persons with hearing loss have a medical evaluation by a licensed physician, preferably a physician who specializes in diseases of the ear, within six months prior to the purchase of a hearing aid.

21 C.F.R. § 801.420. IHS believes that appropriate advice to consumers of their best health interest remains sound policy.

The Regulations also provide that a fully informed adult can elect to forego or waive a medical evaluation. In these circumstances, a purchaser must sign a waiver form indicating that he or she does not wish a medical evaluation before purchasing a hearing aid, so long as the purchaser is specifically advised, orally and in writing, that his or her best health interest warrants a prior medical evaluation.

In adopting the medical evaluation warning statement in 1977 with an express waiver provision, the FDA noted in the Preamble:

a hearing aid device is not an inherently dangerous device and that the number of persons who will in fact require a medical or surgical treatment is relatively small in comparison to the number of individuals who may benefit from amplification. For this reason FDA has attempted to design a medical evaluation requirement to reflect the practical and logistical problems of medical evaluation, the availability of licensed physicians, the mobility of the hearing impaired, and the personal and religious beliefs of those persons who refuse to consult with physicians.

42 Fed. Reg. 9288.

As the FDA evaluates the potential future regulatory framework for the hearing aid industry, it is essential that it recognize that careful formulation of the medical waiver was an integral provision of the original regulations. It was not an exception, or a "loop-hole", but specifically crafted to recognize the issues articulated by the Commissioner in the Preamble of the Regulations. The FDA also took into account the fact that a large percentage of hearing aid purchasers are previous owners and/or invariably have had a prior medical evaluation, although not necessarily in the six months immediately preceding the purchase of a hearing aid. 42 Fed. Reg. 9291-9293. The existence of a waiver form in the files of a dispenser demonstrates compliance, not violation, of the Regulations or use of an unanticipated "loophole."

In fact, most senior citizens obtain medical evaluations regularly. In this regard, we are providing the Committee with a survey commissioned by the Federal Trade Commission ("FTC") in 1985. (Attachment A). The survey was conducted by the nationally recognized research organization Market Facts, Inc. The survey reports on Table III-12 that 79% of repeat hearing aid purchasers had seen a physician prior to their first-time purchase of a hearing aid. This survey, which also reported a high level of consumer satisfaction with hearing aid dispensers (i.e., 76%), was part of the rationale for the FTC's termination of its rulemaking proceeding in 1985.

The only other analysis of the number of consumers who visit their doctors or otherwise sign waivers in conjunction with hearing aid purchases is from the FDA itself. During the 1991 hearing on Vermont's request for exemption from the Regulations' preemption provision, the Boston Office of the FDA confirmed a level of 90% compliance with the FDA Regulations in that state, after excluding records from five dispensers charged with consumer fraud. IHS knows of no data establishing a significant violation of FDA rules, whether compiled by the FDA, state licensing authorities, consumer protection agencies or the industry's self-regulatory procedures.

The issues presented today for reevaluation by the FDA, therefore, were thoughtfully considered through formal rulemaking in 1977. The members of the hearing health team have been identified (i.e., physician, audiologist, hearing instrument specialist). 42 Fed. Reg. 9287. The roles of each health professional have been reviewed and articulated. The underlying and basic findings of the FDA promulgated with the existing regulations remain as valid today as they were in 1977. The FDA did not in 1977, nor can it now, identify any individual who has suffered serious physical harm because of the failure to obtain a medical evaluation prior to the purchase of a hearing aid.

2. THE FDA PROPOSED NEW REGULATIONS

The FDA's current reevaluation of its Regulations appears to focus on the waiver of a prior medical evaluation. IHS believes that the FDA's focus is misplaced. A fully informed adult clearly should not be prevented from making purchase decisions regarding a device which is not harmful or dangerous.

Nonetheless, IHS believes that the development of a standard set of hearing evaluation procedures would be more productive. By developing reasonable and appropriate test protocols, and a uniform patient history questionnaire, the FDA may in fact simplify the existing regulatory structure. A definitive test procedure may more properly determine the need for referral to a physician of the minority of hearing impaired individuals who require a medical evaluation.

The American Council of Otolaryngology, now the American Academy of Otolaryngology (AAO), developed a list of specific otologic conditions which indicate potential medical intervention. These conditions include patient history information (*e.g.*, history of active drainage from the ear within the previous 90 days; acute or chronic dizziness; unilateral hearing loss of sudden or recent onset) and standard audiometric tests (*i.e.*, audiometric air-bone gap equal to or greater than 15 decibels at 500 hertz, 1,000 hertz and 2,000 hertz). AAO and the FDA have acknowledged that hearing aid dispensers are qualified to identify these specific otologic conditions. 42 Fed. Reg. 9290-9291.

A new regulation which delineates these basic test protocols can provide additional assurance to all consumers that uniform and appropriate testing procedures will be conducted. IHS believes that such a procedure would fully protect the hearing impaired public while efficiently utilizing the hearing health care team. IHS would support such a procedure and, if given the opportunity, looks forward to working with the FDA Center For Devices and Radiological Health to develop these test protocols.

3. PROFESSIONAL COMPETENCY STANDARDS

Professional competency and licensure to practice specific professions historically have been within the province of the states. Every state licenses medical doctors, although state laws do not specifically regulate each medical subspecialty, such as otolaryngology. Audiologists are licensed in 42 states. Hearing aid dispensers are licensed in 46 states, with two other states (Alaska and New York) and the District of Columbia requiring simple registration of hearing aid dispensers. Massachusetts and Colorado do not regulate hearing aid providers. Thirty-four states have mandatory continuing education requirements for hearing aid dispensers and four states are currently considering such requirements.

In its Preamble to the existing regulations, the FDA correctly noted that despite efforts by IHS, ASHA, and other professional organizations to develop minimum competency standards for hearing evaluations, state licensing laws do not, and legally cannot, condition licensure upon participation in a private organization or limit licensure to recipients of certification from a private organization. 42 Fed. Reg. 9287. IHS acknowledges that the various state licensing laws are not uniform, and some likely could be strengthened and improved. Additional investigation and enforcement clearly could eliminate any lax professional practices. It is not fair or accurate, however, to generally condemn as inadequate all state laws or enforcement procedures. Many states have not allocated scarce resources to compliance investigations of hearing aid dispensers because the level of consumer complaints has not indicated any problems. As discussed below, the number of complaints filed about hearing aids with state authorities or private organizations such as the Better Business Bureaus, is among the lowest of any product category, on average one-half of one percent (.5%).

IHS believes that any new FDA regulations should delineate and encourage the states to adopt certain minimum levels of experience and training, in addition to specific test protocols, which will advance a more uniform national professional competency standard. The American Association of Retired Persons ("AARP"), while critical of many state licensing laws, has identified the Florida Hearing Aid Licensure Law as an acceptable national model. IHS and its Florida members proposed and supported this law. It requires, among other qualifications, performance-based demonstration of competence. Many other states also require that practitioners demonstrate a performance-based level of competence as part of the licensure process. IHS fully supports these performance-based licensing statutes, and will work with the FDA to develop recommended components for model hearing aid licensing laws.

Contrary to suggestions by Commissioner Kessler on Dateline NBC, the nature and level of skills necessary and appropriate for hearing evaluation and selection of a hearing aid is not synonymous with a post graduate degree in audiology, or any other degree. There are dozens of qualified health professions in the

United States, licensed by states and certified by independent organizations, who do not have college or post graduate credential requirements. Moreover, public health policy clearly demonstrates that formal academic education is not the prerequisite to professional qualification for many roles in the evolving health care system of the 21st century. The President's Health Reform plan is expected to underscore this point.

Studies, surveys and reports by groups such as the American Medical Association, American Hospital Association, American Society of Allied Health Professions, U.S. Department of Veterans Affairs, National Institute on Aging, U.S. Department of Education, U.S. Department of Health and Human Services, and the Institute of Medicine have documented the personnel shortage in allied health, and the impact of such shortages on the cost and accessibility to quality health care. See e.g., Healthy America: Practitioners For 2005, PEW Health Professions Commission (1989). Clearly, the FDA should not now seek to reverse this trend by regulation, and thereby restrict access to quality care, unless it demonstrates a compelling need.

In this regard, it is important to note that while the FDA is reevaluating the existing hearing aid regulations, the Administration and Congress are addressing the larger issues of national health care reform. Two considerations are prominent in every proposal and in every debate: cost and accessibility. Health industry critics point to the under-utilization of the lower cost, accessible and qualified allied health professionals. Simply as a matter of national health policy, the FDA cannot reasonably propose regulations which would effectively decrease or limit the availability of appropriate health care providers and services. We hope and trust that the FDA proposals will reflect a recognition of the important psychology of the hearing impaired. It must propose realistic and achievable regulations which promote easy access to the maximum number of qualified health professionals while maintaining confidence in the integrity and efficiency of the hearing aid delivery system.

A basic finding of the FDA in 1977 remains true today:

The Commissioner recognizes that the accessibility of hearing aid services is of great importance to the quality of hearing aid health care services. The hearing aid dispenser is the most accessible member of the hearing aid health care team and the hearing aid dispenser sees the hearing impaired person with greater frequency than either the physician or the audiologist. For these reasons the Commissioner regards the hearing aid dispenser as an important member of the hearing health care team, strategically positioned within the delivery system to provide the hearing aid user with essential services.

42 Fed. Reg. 9287 (1977).

From IHS' perspective, this debate is not, and should not be, a professional turf dispute between dispensing audiologists and hearing instrument specialists or between audiologists and otolaryngologists. IHS fully appreciates that audiologists have specialized training in the evaluation and rehabilitation of auditory disorders. Many members of IHS are certified audiologists. Audiologists are specifically trained to perform advanced diagnostic tests pursuant to the direction and supervision of physicians.

These specialized tests, however, are not routine, or even indicated, for the vast majority of hearing impaired. Where indicated, a physician would refer a patient to an audiologist for specialized tests. Such a patient initially would be referred to the physician by a hearing instrument specialist who has detected any one of the AAO list of otologic conditions identified by the FDA in 1977. The vast majority of licensed hearing aid dispensers is fully qualified to conduct appropriate hearing evaluation procedures.

Because of concern expressed in the late 1970's that some specialists may lack the skills necessary to accurately measure hearing loss, IHS sponsored the establishment of the NBC-HIS to certify hearing health specialists, including licensed dispensers and audiologists. This organization, now independent of IHS, developed an unbiased examination accepted by many states to measure hearing health specialists' skills and award certification to those candidates who successfully passed the exam. Applicants are required to demonstrate at least two years of licensed or supervised experience and pass a national competency exam. NBC-HIS is accredited by the independent National Commission for Certifying Agencies, which serves as an accrediting body for certifying agencies.

Research involved in the development of the exam by NBC-HIS included a role delineation study, conducted by an independent psychometrician, to determine the skills needed to be a qualified hearing aid specialist. The first role delineation study was conducted in 1981. More recently, in 1991, a second comprehensive study was conducted by Ayres D'Costa, Ph.D., of Ohio State University.

Predicated on established survey methodology, this role delineation study focused on dispensers previously certified by NBC-HIS, licensed hearing aid dispensers, and dispensing audiologists, typically members of ASHA or the Academy of Dispensing Audiologists. The target random sample providing responses represented dispensers certified by NBC-HIS (49%), dispensing audiologists certified by ASHA (26.6%) and licensed hearing aid dispensers (23.8%).

The study indicated that neither education level nor education field significantly predicted performance. The areas of professional responsibility, including problem identification and hearing assessment, were not distinguishable based upon education or specific training in the speech/hearing field. There simply is no valid factual basis to conclude that the experience and skill appropriate to qualified hearing health providers is derived from classroom study or academic degrees. A comparison between the ASHA Preferred Practice Patterns and the NBC-HIS competency model shows remarkable consistency.

Obviously, there are certain services and qualifications which are unique to each professional provider. No one but a physician can make a medical diagnosis. On the other hand, general medical practitioners often have less specific knowledge about hearing impairment, appropriate hearing test procedures or hearing devices than either audiologists or hearing instrument specialists. Similarly, audiologists often perform certain diagnostic tests at the direction and supervision of physician ear specialists which are not generally performed by a hearing instrument specialist or necessary to determine the parameters of a hearing aid fitting. Yet, experienced hearing instrument specialists often have more specific knowledge about the hearing aid devices and ear mold technology than physicians, including physician ear specialists, and many audiologists.

The legal and policy arguments concerning whether a Class I medical device, subject to labeling, advertising and disclosure requirements, should be prohibited from purchase by an informed adult absent medical examination need not be debated at this point. The basic point is that the skills, training and experience necessary to perform, interpret and evaluate appropriate hearing tests are not limited to any one group of providers, nor to providers who have specific educational degrees. Further, the standard audiometric tests (and equipment) are identifiable, and can be performed by qualified hearing instrument specialists, audiologists, and physicians (and often properly trained nurses and physicians); an appropriate consensus on these standard protocols should be readily achievable.

We are confident that the FDA's new rulemaking proceeding will establish, once again, that the hearing aid industry has a unique array of qualified and conscientious providers, each of whom has an important role. IHS looks forward to cooperating with the FDA to produce a balanced and effective regulation which universally will assure an even greater level of consumer protection and confidence in hearing instruments without sacrificing quality care or a competitive marketplace.

The hearing-impaired public, our customers, and the industry, need a constructive and comprehensible uniform regulatory framework. This approach must be designed to eliminate barriers to hearing health care and educate and inform the millions of Americans who can and should benefit from hearing amplification. The regulations must take into account the psychology of the hearing impaired, be realistic and practical in the marketplace and capable of efficient and effective implementation.

3. ALLEGATIONS OF ABUSIVE SALES PRACTICES

Periodically the hearing aid industry has been subjected to allegations of market abuses. In truth and in fact, these claims have never been substantiated or validated. The FTC specifically initiated a rulemaking proceeding which sought to address claims of widespread selling abuses. After nine years of hearings, comments, study and an independent survey by the nationally recognized survey firm of Market Facts, Inc., the FTC terminated its rulemaking proceeding. The 1985 Market Facts survey, commissioned by the FTC, demonstrated that the overwhelming majority of hearing aid buyers were satisfied with their purchases and their providers.

We understand that AARP has released a new study, once again presenting concern over market practices by some hearing aid dispensers, and calling for significant reform. IHS has not seen the final AARP report, but was permitted to review an earlier draft. We should state at the outset that IHS is concerned about any allegations of market sales abuse. Many AARP members are our members' customers.

Because we were understandably concerned with the draft report, we retained a recognized expert to examine the methodology of the study. Based upon the draft report, IHS has identified several areas of concern in which the report appears significantly flawed or draws conclusions inconsistent with its own survey data. Moreover, AARP's conclusions that less than 50% of consumers reported satisfaction with their hearing aids is flatly contrary to three separate and independent surveys over the past three decades, discussed below. This conclusion also is at odds with our own experience with many AARP members. In fact, 70% of our customers typically are repeat purchasers or referrals from our customers and others. Hearing Instruments, Vol. 44, No. 6 (1993).

Nevertheless, IHS welcomes all constructive criticism of the hearing aid industry. Like every profession, the conduct of a few can unjustly tarnish the dedication and commitment of thousands of conscientious providers. Unfortunately, anecdotal data can too easily be extrapolated to categorize the sales practices of an entire industry. We are again placed in the impossible position of refuting the patently erroneous assumption that dispensers would cheat their own customers upon whom they rely for referrals and repeat purchases.

We can assure this Committee that IHS members are fully committed to compliance with all federal and state regulations applicable to the hearing aid industry and to good business practices. We believe that the hearing aid industry has a remarkable and outstanding record of service to the public and compliance with state and federal laws. However, no evaluation of the hearing aid industry's performance can ignore the irrefutable fact that most Americans attach a stigma to hearing loss and most potential purchasers refuse or are reluctant to accept their need for hearing amplification.

IHS has long sought to work with AARP to address its concerns and, more importantly, work to assure that AARP members obtain the best possible service. The Committee must keep in mind that dissatisfaction with hearing aids often reflects nothing more than the dissatisfaction with not hearing "normally." IHS members serve a market where customers deny or ignore hearing loss. When the hearing impaired initially try amplification they are disappointed that their natural hearing is not restored to the same level as when they were sixteen years of age. Yet, despite this customer reluctance, the number of complaints recorded as a percent of sales with state licensing boards, consumer protection agencies and Better Business Bureaus throughout the country is among the lowest in any consumer product category.

The typical rejoinder to this data, of course, is that such data is not a valid indicator of "real" or "actual" complaints. As the FTC found, however, anecdotal stories are no substitute for statistical evidence. The Committee can take state statistics or BBB statistics and multiply by a factor of 100, and still find that the hearing aid industry compares favorably against almost every product category.

The most recent independent survey, conducted by Knowles/NFO Research this year (Attachment B), reported, in contrast to AARP, that 74% of consumers report satisfaction with the ability of the hearing aid to improve their hearing, while only 11% reported dissatisfaction. Seventy-nine percent of purchasers would recommend a hearing aid to a friend, and sixty-nine percent would recommend the person who fit the consumer. The draft AARP report we were permitted to review also noted that 82% of AARP's respondents indicated that they were satisfied with their dispenser. The Committee also will note that the high levels of satisfaction with hearing aid providers reported in the Knowles/NFO survey contrast very favorably to satisfaction ratings compiled by the Conference Board (Oct. 1992) for doctors,

dentists, contact lenses, lawyers.^{1/} This data is entirely consistent with levels of consumer satisfaction reported by Market Facts in its 1985 and 1970 surveys.

It is invalid and unjustifiable to dismiss this data summarily by asserting than senior citizens are more complacent or less likely to complain than other consumers. We are unaware of any study which supports such suppositions, and any person who services senior citizens knows that any such stereotype is totally invalid and insupportable.

In focusing on allegations about our industry, we urge the Committee to carefully consider whether a simple compilation of information on alleged "complaints" filed with state licensing boards, or any other agency, provides a valid basis to extrapolate generalized conclusions about market practices. Similarly, fictitious "shopper" tactics are inherently suspect. Such tactics may be used by television programs such as Dateline NBC to sensationalize a story. The AARP Report is also based, in part, on results of "shoppers" visiting hearing aid providers.

For example, the Department of Commerce for the Commonwealth of Virginia advised Dateline NBC that it had received 51 "complaints" regarding hearing aid specialists from 1988 through 1992. Of that number, only 15 were found to have reported an apparent violation of the Code of Virginia. Yet, even those statistics are meaningless unless NBC asked the Virginia Department of Commerce whether those 15 violations were against one licensed dispenser or 15. Moreover, over 115,000 hearing aids were purchased in Virginia during the relevant time period. The ratio of allegations of apparent failures to comply with Virginia regulation to sales in Virginia (less than .05%) is not statistically greater, and probably lower, than can be determined with respect to any profession or industry.

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	<u>SATISFACTION</u>	<u>DISSATISFACTION</u>
Doctors	9.5%	46.5%
Dentists	9.5%	43.2%
Prescription drugs	21.7%	39.1%
Contact lenses	1.44%	27.4%
Hospital charges	4.8%	64.6%
Lawyers fees	4.6%	64.6%.

Nevada reported to Dateline NBC that it received 47 complaints for the period 1990 to 1993. Of those complaints, 34 were filed with respect to a single office. Each of the individuals at that office who failed to comply with Nevada regulations was sanctioned by the Nevada regulatory authorities. Dateline NBC never reported this fact.

Similarly, sending "shoppers" into hearing aid specialists' offices to determine whether hearing test scores correspond to a "benchmark" test sponsored by another dispenser, typically an audiologist, is unreliable.

First, it must be noted that many dispensing audiologists are direct competitors of hearing aid specialists. The NBC-HIS Role Delineation Study in 1991, described above, belies arguments that an audiologist with a masters degree is any more qualified than an experienced hearing instrument specialist in testing and selecting an appropriate hearing aid.

Second, and more importantly, critical components of hearing tests are very subjective. Most Americans, as the FDA found during its proceedings in the 1970's, refuse to recognize or acknowledge their hearing loss or to seek professional advice. Once professional counseling is obtained, a complete and accurate evaluation of the nature and extent of the individual's hearing loss is dependent on the responses by the client. If a client actually hears the word "speed" and reports to the tester that he or she heard the word "read," a hearing or speech discrimination problem becomes potentially manifest.

Thus, sending "shoppers" into hearing aid specialists' offices to determine whether hearing test scores correspond to a "benchmark" test is inherently unreliable. Hearing evaluation procedures, and answers to a patient history questionnaire, are dependent upon the purchaser's honest and accurate responses.

In Arizona, for example, the State Attorney General used a "shopper" to ascertain if dispensers would conclude that this shopper had a hearing loss when a "benchmark" test concluded that she had "normal" hearing or otherwise was not a candidate for a hearing aid. (This issue as to when a person is a "candidate" for a hearing aid itself has engendered substantial professional debate.)

4. HEARING AID PRICES

Today's hearing aids are highly sophisticated and fairly priced medical devices that have benefited from the industry's continuing investment in research and development and commitment to technological progress. Hearing aids are available from over 9,000 licensed providers. This highly competitive market provides consumers with a wide range of prices, options and services.

As noted, almost all traditional hearing instrument specialists include the cost of testing, fitting, instruction, follow-up care and counseling with the price of the hearing aid. Other dispensers may charge separately for testing, follow-up care and counseling. Almost all providers offer purchase-rental options. When hearing aids are sold at a "bundled" single price, almost the entire cost of the instrument is refundable, including testing and follow-up care services. When instruments are sold separately from testing and follow-up counseling services, only the price of the hearing aid is refundable.

5. PRODUCT PERFORMANCE CLAIMS

The IHS Code of Ethics and good business practice require truthful and accurate advertising. IHS believes in the importance of educating the public about the benefits of hearing aids and, along with the entire industry, seeks to motivate those who need hearing assistance to invest in hearing aids with greater confidence and realistic expectations. Product advertising, and industry supported public service announcements by the Better Hearing Institute, are the predominant source of information to consumers.

IHS fears that the FDA has embarked on an unreasonably and unduly restrictive regulatory scheme for hearing aid performance claims. Hearing aids do help individuals hear better and are critical to the enjoyment of life by millions of Americans. Ask Bob Hope, Arnold Palmer, President Ronald Reagan, Phyllis Diller, Bobby Unser, Leslie Nielson or Richard Thomas -- they all suffer from some type of hearing loss and now, through BHI, publicly inspire and encourage others to benefit as they have from available hearing help.

IHS has documented that this Arizona "shopper" filled out a background information form for the various "target" dispensers wherein she indicated that she had difficulty hearing in certain conditions. Were these responses false? Were her responses to the "benchmark" test procedures accurate? The answers to questions on a case history form, and responses to audiometric test procedures, obviously are essential factors in any evaluation as to whether the "shopper" had "normal", "moderate", or "severe" hearing loss. It is self-evident that a "shopper's" responses would explain why one dispenser would conclude that she had a "moderate" loss whereas another dispenser may have concluded, with more accurate responses, that her hearing was "normal".

No one on the hearing health care team can seriously contest the importance of consumer responses to patient histories and test procedures in a hearing evaluation. Unfortunately, the media and other groups often seek to create or document controversy. The programs and reports underestimate or ignore professional debate as to professional qualifications, as well as legitimate debates as to the level of hearing loss which may benefit from hearing amplification. Perhaps professional debate and turf issues are inevitably part of the health care system. However, the fact remains that objective and independent data corroborate and confirm the high level of consumer satisfaction with their hearing aid instruments and providers.

All of the objective data from state licensing authorities, BBB national statistics and independent survey data cannot be wrong. IHS understands that certain hearing aid providers may suggest that their services or credentials are superior to others. However, IHS vigorously contests any such assertions. In fact the hearing impaired public has a unique array of qualified providers, and at a time when the Congress is seeking to contain health care costs and increase accessibility to the American public, particularly senior citizens, it would be remarkable for FDA to exclude or allow states to exclude, either directly or indirectly, a group of qualified providers such as IHS members and providers certified by NBC-HIS.

Everyone relies on his or her sense of hearing for so many facets of life -- communicating thoughts and ideas, relaxation, entertainment and even safety. Hearing loss effectively can dislocate individuals from their social, family and employment environment. Hearing loss adversely affects self esteem and an individual's communicative ability. The FDA should not need clinical testing to establish the obvious. Hearing instruments can and do provide valuable and important hearing assistance. Hearing instruments don't "change" hearing, they access sound so hearing impaired persons can more efficiently process it.

By using hearing aids the vast majority of the hearing impaired can continue to lead productive, full and successful lives. Dr. Koop said it best on the Today Show on July 7, 1993.

I found myself making inappropriate responses to questions. I was standing around looking dumb, because I couldn't hear. And I think the most important thing for any person who has a hearing aid is to understand what the expectations of that might be. . . . We should talk to the people with whom they live, because the people in the household of a hearing impaired person are very important to that individual's becoming accustomed to the hearing aid. . . . I love to change the batteries in my hearing aid, because I want the public to know that they are no more embarrassing than wearing glasses.

The present FDA initiatives to restrict hearing aid performance claims are regulatory overkill. The FDA appears to be on a course which could impose significant barriers to communication of basic and important information to hearing impaired consumers by requiring clinical data under the FDA's comprehensive 510(k) process. Much of the FDA's new regulatory focus is related to noise and speech intelligibility, as well as any other performance claim. See Letter from FDA to Manufacturers regarding advertising claims (Attachment C). The new "labeling" requirements virtually eliminate performance claims and effectively dictate qualifying statements, the effect of which will be that few prospective purchasers are likely to overcome the preexisting reluctance to seek hearing assistance.

Information about expectations and performance characteristics of the hearing aid can be communicated accurately, truthfully and positively without imposition of the regulatory pre-clearance and onerous qualifications demanded by the FDA. The FDA's directives effectively could prevent any meaningful communication to the hearing impaired out of fear any

statement may violate FDA's edicts. This is not in the interest of the hearing impaired public, and the Committee should work with the FDA to assure that appropriate information is not being unnecessarily withheld from the consumer because of the dramatically new position taken by the FDA. Indeed, the FDA should improve the existing Regulations by more positively and affirmatively providing appropriate information about hearing aids and hearing aid providers.

The FDA can, and should, however, modify its Regulations to specifically address mail order hearing aid sales and sales of comparable devices (such as the "Whisper 2000").

6. CONSUMER PROTECTION

A. Federal

At the federal level all hearing aid dispensers must adhere to comprehensive federal regulations of the FDA governing hearing aid sales practices and the FTC governing advertising. The FDA rules require that a prospective purchaser be advised to obtain a medical evaluation of hearing loss within six months prior to obtaining a hearing aid. Once informed of appropriate FDA disclosures an adult customer may sign a waiver in lieu of a medical examination. A user instructional brochure containing all relevant information must be provided to prospective purchasers.

Under the Federal Trade Commission Act, the FTC can take action against companies for (1) false or deceptive advertising, (2) for any violation of the Magnuson-Moss Warranty Act and (3) for violation of the Cooling-Off Rule regulating sales away from the regular place of business. Recently, the FTC filed complaints against several dispensing audiologists for falsely representing that audiology and hearing evaluation tests were reimbursed by Medicare.

B. State

State licensing laws have previously been described. The enforcement budgets and complaint procedures of each state, of course, vary. Many states have successful programs and it is an unfair and unreasonable assertion that all state programs are ineffective.

C. Dispute Resolution

In addition to the BBB network, media "action lines", state and local consumer advisory organizations, IHS sponsors a toll-free Hearing Aid Helpline (1-800-521-5247), which is available to provide sources and contacts for consumers wishing to file complaints. IHS also offers to mediate consumer grievances in many instances.

D. Trial Rental Options

Most hearing aid dispensers offer and promote a trial rental or purchase option program, and prospective hearing aid purchasers should look for this assurance. At present IHS believes that fourteen states (California, Connecticut, Kentucky, Maine, Minnesota, New Hampshire, New York, Oregon, Tennessee, Vermont, Virginia, Washington, West Virginia) and The District of Columbia, have laws which require a trial period for all hearing aid sales. IHS promotes and supports market developed trial rental options but opposes state mandated procedures because they are rigid and inflexible, and can impede a post-fitting counseling program in conjunction with rental-purchasing options.

More importantly, mandatory return laws may force dispensers to unbundle the combined price of the hearing aid and related services. This would have the adverse consequence of actually increasing the price of purchase options to consumers. Given the wide availability of market options, a government mandated program would be counter-productive and effectively substitute high cost regulation for fully effective marketplace programs. Less than 10% of hearing aids sold under purchase options were returned.

Before completing the hearing aid purchase, the consumer should reach a definite agreement with the dispenser about the details of the transaction. Most hearing aid dispensers provide trial periods of at least 30 days in length. If the hearing aid is provided outside the dispenser's place of business, there is a mandatory three-day cooling-off period. During this cooling-off period, a refund is guaranteed to the consumer by FTC regulations.

Additionally, manufacturers provide a comprehensive one-year warranty; some even include: (a) complete replacement if the instrument is lost, stolen or damaged beyond repair, (b) no charge for repairs due to mechanical failure of any type during the warranty period; (c) replacement of the instrument if physical ear size changes; and (d) adjustment of the acoustical performance of their instrument if the user's hearing requirements change. Many manufacturers will offer 30-day return periods to the dispenser for the price of the hearing aid, but not, of course, for the testing and counseling services.

7. VERMONT PETITION

In 1990, the State of Vermont applied to the FDA for exemption from the federal regulatory requirement that a waiver be made available to all adult hearing aid purchasers. Vermont sought permission to enforce a state law that would require all first time hearing aid purchasers to receive a medical evaluation. The FDA received written comments from the public on Vermont's petition and conducted an oral hearing on this petition in April 1991.

Virtually all public commenters testified against granting Vermont's petition on the grounds that the state did not present adequate evidence that the waiver is being abused and, further, had made no effort to enforce existing FDA regulations regarding disclosure of the importance of a medical evaluation. Commissioner Kessler recently indicated informally that he is prepared to grant Vermont's petition, possibly simultaneous with publishing a revised proposed rule.

The Committee should urge Commissioner Kessler not to grant the Vermont petition. Approval of the petition would adopt a position flatly contrary to the FDA's decisions on six other states' petitions and would come at a time when the FDA already has announced a decision to reevaluate the entire federal standard.

CONCLUSION

IHS greatly appreciates the opportunity to submit these written comments and is prepared to discuss any of the issues discussed herein or of interest to the Committee.

Herbert D. Gorlin
President

Robin L. Holm
Executive Director

International Hearing Society

ATTACHMENT A

A Description of the
Experiences of Recent
Hearing Aid Purchasers

Presented to:

Federal Trade Commission
6th and Pennsylvania Avenue, N.W.
Washington, D.C. 20580

Presented by:

Market Facts, Inc.
1730 Pennsylvania Avenue, N.W.
Washington, D.C. 20006

I. EXECUTIVE SUMMARY

A national sample of 847 persons who identified themselves as having purchased a hearing aid in the past 2 years was surveyed by mail in order to obtain information on their experiences in the following areas:

- Background Characteristics: Length of ownership, type of aid, and extent of use
- Reasons for purchase
- Who determined the power and tone specifications for the hearing aid
- Physician consultation
- Pre-purchase information and beliefs
- Selection of the seller
- Trial period and warranty availability and use
- Satisfaction with the hearing aid

This summary highlights the major findings of the study; a more detailed analysis is presented in Chapter III.

Respondent Overview

Participants in the survey can be summarily described as follows:

- Almost 90% of the hearing aid wearers were 50 years old or older. A majority (61%) fell in the 60-79 age bracket.
- Sixty-five percent of the hearing aids purchased in the past two years by survey respondents were the wearer's first hearing aid. Thirty-two percent were replacement aids, and 5% were additional aids purchased for the other ear.

- Forty-six percent of the hearing aids most recently purchased by respondents were purchased less than a year before the survey. Another 45% were purchased 1-2 years prior to the survey, and 9% of the respondents had indicated purchasing a hearing aid within two years of the screening questionnaire but indicated 2-3 years on the actual questionnaire.
- Seventy-one percent of the respondents wear one hearing aid while 29% wear two aids. Sixty-six percent wear "in the ear" aids, and 33% wear the "over the ear" type. Almost all aids were purchased new (98%) rather than used or reconditioned.
- Seventy percent of the wearers wear the hearing aid most or all of the time. Almost two-thirds (64%) wear them more than 25 days per month, and 61% wear them more than 8 hours per day on the days the aid is worn.

Reasons for Purchase

The types of hearing problems prompting respondents to get hearing aids are reviewed below:

- Forty-six percent of the respondents said the hearing problem was diagnosed as sensorineural only. Eleven percent cited both conductive and sensorineural problems, and 8% said the problem was conductive only. Thirty-five percent did not know the diagnosis of their hearing problem.
- Four hearing difficulties were cited by a majority of respondents as *strongly applying* to them prior to purchasing a hearing aid. Seventy percent said having to ask people to repeat themselves strongly applied to them while 61% mentioned having a hearing test that revealed a problem as strongly applying. Also mentioned as strongly applying to them by a majority of respondents were not being able to hear in crowds or at parties (58%) and friends or relatives complaining about their hearing (51%).

Pre-purchase Information and Beliefs

Respondents were asked about their sources of information on hearing aids as well as their beliefs about what the hearing aid would accomplish. The results are summarized below.

- The most commonly mentioned sources of information on hearing aids were audiologists (45%), physicians (42% - mostly ear specialists), and dealers/salespersons (35%).
- Most respondents appear to have obtained information on hearing aids from the person from whom they purchased the aid. A majority of the persons who bought from each of these types of sellers (physicians, audiologists, and others) mentioned that source as supplying them with information.
- Almost all respondents believed, prior to purchasing, that hearing aids would probably make it possible to understand normal conversations (92%) and would probably improve hearing (90%). Sixty-nine percent thought the hearing aid would probably make it possible to distinguish voices and sounds, especially in crowds. The fraction of respondents who thought the aid would possess these characteristics and for whom this was important in the purchase decision was somewhat smaller in each case - 91%, 88%, and 65%, respectively.

- Less than one-third of the respondents thought the hearing aid probably would restore normal hearing (30%) and provide minimal hearing for profound deafness (31%). Even fewer thought it would stop deterioration of hearing (14%) or cure nerve damage (4%). The fraction who thought the aid would possess these characteristics and for whom this was important in the purchase decision was 28%, 26%, 12%, and 2%, respectively.

Physician Consultation

A primary concern of the study was the extent to which physicians were consulted by purchasers of hearing aids. Questions were asked as to whether physician exams were recommended, whether they occurred, and whether physicians who were seen made recommendations concerning the hearing aid.

- Forty-two percent of the respondents reported seeing or hearing something that suggested that they see a physician prior to purchasing a hearing aid. Twenty-five percent of all respondents said that the seller of the hearing aid recommended a physician exam.
- Sixty-four percent of the respondents actually saw a physician about the hearing problem prior to purchasing the most recent hearing aid. Of these, 92% said they consulted an ear specialist, and 15% mentioned a general practitioner/internist. Those whose most recent hearing aid was a first aid were significantly more likely to have consulted a physician prior to purchase (72%) than were those whose most recent aid was a replacement (51%) or an aid for a second ear (48%).
- Nearly all (94%) of the persons who consulted a doctor did so before ever seeing the person from whom the hearing aid was purchased. Sixty-one percent of those who saw physicians did so less than three months prior to purchasing the hearing aid.
- Eighty-two percent of the respondents who saw a physician said the doctor recommended a hearing aid. Thirty-two percent said a specific seller was recommended, and 28% received model recommendations from the physician.

Determination of Power and Tone

Findings related to the determination of power and tone for hearing aids appear below.

- Fifty-three percent of the respondents received the determination of hearing aid specifications from an audiologist, while 33% cited hearing aid dealers/salespersons, and 13% mentioned physicians.
- Seventeen percent of the respondents said the examination for power and tone was done in the home. Where the determination was made by someone other than a physician or audiologist, the incidence of this phenomenon was 36%.

- Sixty-three percent of the hearing aid wearers reported receiving a recommendation of a specific brand of hearing aid from the person who determined the specifications for the hearing aid. Fifty-one percent heard recommendations of specific sellers of hearing aids from the person who fit them. Audiologists and dealers/salespersons were more likely than physicians to make brand and seller recommendations.

Selection of Seller

The major findings on the process through which hearing aids are purchased are summarized below:

- The majority (55%) of hearing aid purchasers bought their aid from a dealer or salesperson other than an audiologist (38%) or physician (6%).
- Most (80%) of the respondents contacted only one seller of hearing aids. Among those who did contact more than one, the reasons given for doing so included finding a better aid for the hearing problem (50%), finding a better price (36%), finding a seller closer to home (22%), and availability of a trial period (19%).
- Most hearing aid purchasers initially contacted the seller by either calling them on the telephone (36%) or walking into an office (31%). Twelve percent were contacted by a seller after sending in a card. Of these, 88% expected to be contacted upon sending the card. Less than 1% of the respondents said they purchased the aid from a seller who came to their home without calling.
- Nearly one-third (32%) of the respondents gave no single primary reason for selecting the seller they chose. Fourteen percent mentioned an audiologist's recommendation, and 10% cited the recommendation of a physician as a primary reason.
- Reasons deemed most important for the selection of the particular hearing aid were availability of a warranty (94% very or somewhat important), availability of a trial period (84%), audiologist's recommendation (83%) and reputation of hearing aid dealer/salesperson (79%).
- The price for one hearing aid ranged from less than \$100 to \$1400. The mean price was \$476 and the median \$464. The mean price for two aids was \$932 and the median \$945.
- Only 15% of the respondents said hearing aid costs were covered all or in part by some form of insurance. Of those who were covered, 52% said insurance covered the entire cost of the hearing aid.

Trial Period and Warranty Availability and Use

A summary of the findings on the availability of trial periods, the conditions on their use, and the availability of warranties is presented below.

- Sixty-four percent of the hearing aid purchasers were offered a trial period with their purchase while 20% reported that they were not, and 16% did not know. Persons purchasing the hearing aid within a year prior to the survey (70%) were more likely to have been offered trial periods than those whose purchases were made one to two years (59%) or two or more years (65%) prior to the survey. There were no significant differences in trial period availability according to whether the respondent resides in a state requiring trial periods.
- Of those that were offered a trial period, 71% were told of the trial period by the seller without having to ask. Only 3% of those offered a trial period said the hearing aid would have cost more with the trial period than without. The mean price reported for one aid was virtually the same for those purchasing with a trial period (\$483) as for those purchasing without a trial period (\$482). For two aids, the mean price reported by those who did not receive trial periods (\$996) was significantly higher than the mean price reported by those who received trial periods (\$897).
- Thirty-five percent of the respondents said they would have been willing to pay a higher price for the hearing aid in order to receive a trial period. Those for whom a trial period was available were significantly more likely (42%) to express this willingness than were those for whom a trial period was not available.
- Of those who were offered a trial period, 93% received a trial period with the purchase. Fifty-nine percent of these said the trial period lasted 30 days or less. Twenty-two percent did not know the length of the trial period.
- Of those who reported receiving a trial period 24% said they would have had to try another aid from the same seller as a condition of the trial. Eight percent said they would have had to attend training sessions on the use of the aid, and 3% said they would have been required to obtain a doctor's letter saying the aid was not suitable in order to return the aid for a refund.
- Concerning the type of refunds associated with trial periods, 45% of the respondents said they would have received a 100% refund if they had returned the aid during the trial period. The most common charge that was not refundable was that for earmolds, the mean cost of which was \$41.
- Seventy-seven percent of the respondents who received trial periods said the hearing aid performed as expected during the trial period. Of the 23% who said the aid did not perform as expected, 69% mentioned the problem of amplification of unwanted noises while 42% mentioned discomfort from wearing the aid. Mentioned by about one-third of those not satisfied during the trial period were difficulty hearing in crowds (35%), feedback from the hearing aid (34%), and difficulty hearing telephone conversations (32%).
- Ten percent of the respondents who received trial periods returned the hearing aid during the trial period. Fifty-one percent of these either received another aid and kept it or got an adjustment on the original aid. Forty-four percent returned the original hearing aid and received a refund, and 5% returned the original aid for a second one which was also returned.

Customer Satisfaction

Findings on the respondents' degree of satisfaction both with the seller and the hearing aid are reviewed below.

- Of the respondents who believed the aid would perform in this way and to whom this belief was important in the purchase decision, 95% said the hearing aid somewhat or definitely made it possible to understand normal conversations, and 94% said the hearing aid somewhat or definitely improved their hearing. Eighty-two percent said the aid somewhat or definitely made it possible to distinguish voices and sounds especially in crowds, and 79% said it somewhat or definitely restored normal hearing.
- Seventy-six percent of the respondents said they would return to the same seller were they to buy another hearing aid. Those buying from audiologists were most likely to say they would return (81%) followed by those buying from physicians (78%) and other sellers (72%). The most common reason given for both returning and not returning was quality of service.
- Eighty-four percent of the respondents said they were satisfied with the ability to hear with the hearing aid. Though most respondents in all subgroups examined were satisfied, those expressing the highest levels of satisfaction were:
 - Those whose power and tone specifications were determined by physicians or audiologists
 - Those purchasing from audiologists
 - Those whose examinations were performed outside the home
 - Those who consulted physicians prior to the first or most recent purchase
 - Those who purchased the aid with a trial period
- Among the 10% expressing dissatisfaction, the problems most commonly mentioned were amplification of unwanted noise (74%), inability to hear in crowds (67%), having to ask people to repeat themselves (61%) and feedback from the hearing aid (54%).

D. Physician Consultation

Another primary concern of the study was the extent to which hearing aid purchasers consult with physicians prior to purchasing hearing aids and the impact of consultation. Respondents were thus asked whether they had seen or heard anything suggesting that they get a physician's examination prior to purchasing a hearing aid, whether the person who sold them the aid recommended seeing a physician, and whether, in fact, they saw a physician before purchasing the hearing aid.

As indicated in Table III-11, 42% of the respondents affirmed exposure to some suggestion of a physician exam while 46% said they experienced no such exposure, and 12% could not recall whether they had seen anything suggesting an exam. All respondents were then asked whether or not the seller of the hearing aid recommended a physician examination, and 29% indicated that the seller did recommend seeing a physician. Physicians (29%) and audiologists (29%) were mentioned slightly more often than other types of sellers (23%) as having recommended exams, but this difference is not significant at the 95% confidence level.

Table III-12 indicates that 64% of the respondents actually saw a physician about their hearing problem before purchasing the most recent hearing aid. Among those whose most recently purchased hearing aid was their first hearing aid, 72% consulted a physician prior to purchase while 51% of those whose most recent purchase was a replacement aid and 48% of those whose most recent purchase was an aid for a second ear consulted a physician prior to purchase. Among those respondents who had purchased a hearing aid prior to the most recent one, 79% reported seeing a physician about the hearing problem before buying the earlier aid. Of these respondents who saw a physician prior to purchasing an earlier first hearing aid, 57% reported seeing a physician prior to purchasing the most recent aid as well. In contrast, among those who purchased an earlier aid without a physician consultation, 24% saw a physician before purchasing the most recent aid.

As to the type of doctors consulted about the hearing problem, most respondents who saw a physician prior to the most recent purchase indicated that they saw ear specialists (92%) as opposed to general practitioners/internists (15%). Obviously, some respondents saw both types. For those who saw a doctor prior to an earlier purchase, 88% described the doctor as an ear specialist, and 15% said they consulted a general practitioner/internist.

As shown in Table III-13, nearly all (94%) of the respondents who saw a physician prior to purchase did so before their initial contact with the seller. Eleven percent reported seeing the doctor after being in contact with the seller; thus, some respondents must have consulted the doctor both before and after seeing the seller. A plurality of respondents (41%) consulted with the physician less than one month before purchasing the hearing aid. An additional 20% reported physician consultations 1-3 months prior to purchase, and 11% saw a doctor 3-6 months before buying the hearing aid. Nineteen percent reported doctor visits more than 6 months previous to purchasing the hearing aid.

Respondents who consulted with physicians prior to purchasing their most recent hearing aid were asked if the physician recommended that they get a hearing aid and if the physician suggested a particular model or seller of hearing aids. The results of this item are presented in Table III-14. Most (82%) of the respondents who saw physicians about the hearing problem were told that they should purchase a hearing aid. However, only 28% received a recommendation of a specific model of hearing aid, and only 32% recalled hearing a suggestion of a specific seller from the physician.

TABLE III-11
RECOMMENDATION OF PHYSICIAN EXAMINATION

	<u>%</u>
<u>See or Hear Anything Suggesting Physician Exam?</u>	
Yes	42
No	46
Don't recall	12
(BASE)	(829)

Qu. 10: Before purchasing your (or the wearer's) current hearing aid, had you seen or heard anything that suggested a physician examination is recommended prior to purchasing a hearing aid?

<u>Seller Recommend Physician Exam?</u>	<u>Total</u> <u>%</u>	<u>Type of Seller</u>		
		<u>Physician</u> <u>%</u>	<u>Audiologist</u> <u>%</u>	<u>Other</u> <u>%</u>
Yes	25	29	29	23
No	67	63	66	68
Don't recall	8	8	6	10
(BASE)	(814)	(38)	(270)	(410)

*Percentages may add to more than 100% due to rounding.

Qu. 11: Did the person from whom the current hearing aid was bought ever recommend seeing a physician about the hearing problem?

TABLE III-12

PHYSICIAN CONSULTATION

		<u>Was Physician Seen for Most Recent Hearing Aid?</u>				<u>Was Physician Seen for First (Earlier) Hearing Aid?</u>
		<u>Total</u>	<u>First Aid</u>	<u>Replacement Aid</u>	<u>Aid for 2nd Ear</u>	
		<u>%</u>	<u>%</u>	<u>%</u>	<u>%</u>	
Yes	64	72	51	48	57	24
No	36	29	49	22	43	76
(BASE)	(811)	(513)	(254)	(31)	(201)	(54)
						(257)

*Percentages may not add to 100% due to rounding.

Type of Physician

General Practitioner/ Internist	15	18	6	13	N/A	17
Ear Specialist Physician	92	90	98	87		88

*Percentages add to more than 100% because multiple responses were accepted.

Qu. 5 & 6: Did you (or the wearer of the hearing aid) see a physician about the hearing problem before purchasing the most recent (first) hearing aid? Which kind?

TABLE III-13

TIMING OF PHYSICIAN CONSULTATION

<u>When Physician Was Seen</u>	<u>%</u>
Before seeing person from whom aid was purchased	94
After seeing person from whom aid was purchased	11
(BASE)	(505)

*Percentages add to more than 100% because multiple responses were accepted.

Qu. 7: Did you (or the wearer) see the physician before or after seeing the person from whom you purchased the current hearing aid.

<u>How Long Before Purchase Was Physician Seen?</u>	
Less than 1 month	41
1 month to less than 3 months	20
3 months to 6 months	11
Longer than 6 months	19
Don't remember	10
(BASE)	(505)

*Percentages do not add to 100% due to rounding.

Qu. 8: How long before actually purchasing the current hearing aid did you (or the wearer) visit a physician about the hearing problem?

TABLE III-14

RECOMMENDATIONS PROVIDED BY PHYSICIAN

<u>A Hearing Aid?</u>	<u>%</u>
Yes	82
No	15
Can't recall	3
(BASE)	(475)

<u>A Specific Model of Hearing Aid</u>	
Yes	28
No	67
Can't recall	5
(BASE)	(376)

<u>A Specific Seller of Hearing Aids</u>	
Yes	32
No	64
Can't recall	4
(BASE)	(381)

Qu. 9: Did the physician recommend any of the following to treat the hearing problem?

The Marketing Edge

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Consumer Satisfaction with Hearing Instruments in the United States

Sergei Kochkin, Ph.D.
Knowles Electronics, Inc.

Introduction

A number of studies have sought to access consumer perceptions of hearing aids. This paper reports on a survey taken in 1984 and on research conducted by Knowles Electronics in 1991.

Overall, consumers give high marks to hearing aids. They feel that they generally are satisfied with hearing aids and that their quality of life is enhanced by hearing aid use.

FTC Study

The most recent government sponsored study in the U.S. on consumer satisfaction with hearing instruments was conducted on behalf of the Federal Trade Commission (FTC) in 1984 by Market Facts, a market research firm. The FTC study was conducted among 847 hearing instrument owners who reported their hearing instruments were two years or less in age. Responses were confined to respondents who held specific beliefs about what the hearing instrument was capable of.

The ratings given by this sub-population of hearing instrument owners were outstanding:

- 84% indicated they were very satisfied or somewhat satisfied with the ability to hear with the hearing instrument; only 10% were dissatisfied with the hearing instrument.
- 76% indicated they would return to the dispenser to purchase their next hearing instrument.

Biography

Dr. Sergei Kochkin is Director of Market Development and Market Research for Knowles Electronics, Inc., Itasca, Illinois; a Board member on the Better Hearing Institute and a member of the Collaborative Marketing Committee.

- 95% indicated the instrument made it possible (somewhat/definitely) to understand normal conversation.
- 94% said it improved (somewhat/definitely) their hearing.
- 82% said it helped them distinguish sounds and voices in crowds (somewhat/definitely).
- 79% said it restored their hearing (somewhat/definitely).

Knowles/NFO Research

In October 1991, a short screening survey was mailed to 80,000 members of the National Family Opinion Panel (NFO). The NFO panel consists of households that are balanced to the latest U.S. census information with respect to market size, age of household, size of household and income within each of the nine census regions, as well as by family versus non-family households, state (with the exception of Hawaii and Alaska), and the nation's 25 largest metropolitan statistical areas.

This screening survey helped identify more than 13,000 households with at least one person indicating a hearing difficulty. In December 1991, extensive surveys were sent to 3,000 hearing instrument owners and 3,000 non-owners with a hearing difficulty. The data for this paper is based on usable survey returns from 2,323 hearing instrument owners.

This study asked respondents to indicate the impact the product had on their quality of life and whether or not they would recommend hearing instruments to friends, repurchase their

current brand, return to their dispenser and the extent to which the product was worn. In addition, using a "very satisfied, satisfied, neutral, dissatisfied, very dissatisfied" scale, respondents rated hearing instruments on 42 factors.

The table documents 46 measures of consumer satisfaction with hearing instruments in the U.S. market. In addition, the last column in the table shows the ratio between satisfied consumers and dissatisfied consumers.

Overall Satisfaction

58% of current hearing instrument owners reported that overall they are satisfied or very satisfied with their hearing instrument; 20% report they are dissatisfied. Satisfaction ratings are however significantly related to the age of the hearing instrument (data not shown). Owners with one year old hearing instruments report a 66% satisfaction rating and a 12% dissatisfaction rating. This can be compared to 5 year old hearing instruments (56% satisfied/19% dissatisfied) and 10 year old hearing instruments (48% satisfied/29% dissatisfied).

Consumer Experiences

Similar to the 1984 FTC/study, the industry received high marks as evidenced by the following consumer attitudes/behaviors:

- Nearly 8 out 10 owners would recommend a hearing instrument to a friend with a hearing loss.
- Approximately 7 out of 10 owners would recommend a specific dispenser.
- Two out of three consumers would repurchase their current brand.
- 65% report that hearing instruments have significantly improved the quality of their life; less than 7% report their hearing instrument has not improved the quality of their life.
- 12% of owners never use their hearing instruments.

Comparing the extremes of satisfaction (very satisfied, very dissatisfied—analysis and data not shown), the very satisfied individual is:

- 12 times more likely to repurchase their current brand,

- nearly 4 times more likely to generically endorse hearing instruments,
- nearly 7 times more likely to recommend the dispenser who fit their hearing instrument.

Satisfaction with Hearing Instruments

Consumer satisfaction with ten hearing instrument product features and nine performance/value factors are next shown in the attached table. With respect to product features, nearly 8 out of 10 consumers report satisfaction with fit and comfort of the hearing instrument; less than 8% report dissatisfaction. Similarly high ratings were received for hearing instrument size, appearance, visibility and ease of volume adjustment. Product features receiving ratings in the 60% range include: packaging, frequency of cleaning, warranty, and ease of battery change. The lowest rated product feature was on-going expense (49%).

With respect to product performance, nearly 9 out of 10 consumers are satisfied with battery life and 7 out of 10 with product reliability. Nearly 3 out of 4 consumers report satisfaction with the ability of the hearing instrument to improve their hearing while only 11% report dissatisfaction. Approximately half of the owners believe that sound quality and the ability to localize direction are satisfactory. The most severe ratings are given to whistling/feedback/buzzing (38% satisfaction/33% dissatisfaction) and the ability to use the hearing instrument in noisy situations (28% satisfaction/47% dissatisfaction). Noteworthy is the perception by only slightly more than half of the respondents that hearing instruments have satisfactory value. In the survey, we specifically defined the term value for the consumer as "performance versus money spent".

Satisfaction in Listening Environments

Consumers were asked to rate their level of satisfaction in 10 listening situations from one-on-one communication to large groups. Nearly 9 out of 10 owners report satisfaction with hearing instruments in one-on-one communication and 7 out of 10 while watching TV. However, satisfaction ratings decline dramatically as a function of the complexity (noisiness) of the

listening environment with large group environments receiving the lowest ratings (25% satisfaction/49% dissatisfaction).

A device that improves hearing in limited situations is predicted to result in lower satisfaction ratings, lower repurchase rates, and more negative "word-of-mouth" advertising. In a more detailed segmentation analysis of our data, we have found strong associations between satisfaction and the variety of listening environments in which the consumer's hearing was improved. Considering the segment of consumers who experience improved hearing in no listening environment (8.8% of owners), they report an overall satisfaction rating of only 6%. This should be compared to the 13.6% of owners reporting satisfaction in all 10 rated listening situations; their satisfaction rating was 91.5%. Forty percent of the current hearing instrument owner market report satisfaction in 70% of the listening environments measured in this study. Their combined overall satisfaction rating is 86%. Clearly this industry has the technology and the skill to achieve 80-90% satisfaction ratings.

Satisfaction with Dispenser Service

Consumer satisfaction with twelve measures of dispenser service are next shown in the attached table. The ratings given to dispensers are outstanding. All but two of the ratings are close to 90% satisfaction ratings. Nearly 8 out of 10 consumers are satisfied with the dispenser's explanation of what to expect from hearing instruments and post-purchase service. Less than 7% of consumers are dissatisfied with the dispenser's explanation of what to expect from hearing instruments. One can infer that dispensers are, in general, providing realistic expectations to consumers.

Conclusions

This study, using more stringent measures than the previous U.S. study conducted on behalf of the FTC, demonstrates that the industry, its product, and the dispenser receive high ratings as reflected by likelihood of repurchase, returning to the dispenser and endorsing hearing instruments to friends and relatives. Less than 7% of owners indicate the product has not improved their quality of life. Roughly 6 out of 10 consumers report overall satisfaction with the hearing instrument compared to 2 out of 10 dissatisfied. However, dissatisfaction ratings for newer products are more in agreement with the 1984 FTC study.

The data clearly show where the hearing aid industry is doing a good job in satisfying hearing instrument owners and where it could improve. Areas needing improvement from the consumers' perspective (based on the correlation between the overall rating and detailed ratings) are: perceived value, product reliability, the variety of listening environments in which their hearing instruments improve hearing, sound quality and on-going expense.

It would be useful to compare hearing instrument satisfaction ratings to other relevant products or services outside of the industry. Recent research on consumer perceptions of value for various services and products were published by the Conference Board (October, 1992). Using a "good", "average", "poor" value scale, the following ratings were achieved: Doctor's fees (9.5% good value/46.5% poor value), dentist fees (9.5% good/43.2% poor), prescription drugs (21.7% good/39.1% poor), eyeglasses (19.4% good/ 27.8% poor), contact lenses (14.4% good/27.4% poor), lawyer's fees (4.6% good/59.8% poor), and hospital charges (4.8% good/64.6% poor). While the results are not directly comparable because of the different measurement scales, in the Knowles study, 52% of hearing instrument owners indicated that they were satisfied with the value they received from their instrument; 22% were dissatisfied with the value. Hearing instruments receive more than twice as many "good value (satisfied)" ratings as "poor value (dissatisfied)" ratings. This finding should be compared to the measurements taken by the Conference Board, where "poor value" ratings consistently exceed "good value" ratings sometimes by a factor as high as 13 negatives per positive response (e.g. hospital fees).

The 1984 FTC study and the 1991 Knowles Electronics study indicate a high level of satisfaction with hearing aids. The surveys also indicate that consumers feel hearing aids improve their quality of life.

The surveys identify a number of areas in which satisfaction can be enhanced. Compared to consumer satisfaction with other products, the hearing aid industry seems to be doing very well in meeting consumer expectations and providing products that satisfies its customers.

U.S. Hearing Instrument Satisfaction Ratings 1981

	% Very Dissatisfied	% Dissatisfied	% Total Dissatisfied	% Neutral	% Total Satisfied	% Satisfied	% Very Satisfied	Satisfied per Dissatisfied
Overall Satisfaction	7	13	20	22	58	38	20	2.8
Consumer Behavior								
Quality Of Life (Note 1)		7	28	65	41	24	9.9	
Recommend Hearing Aids To Friend (Note 2)		7	14	79			11.9	
Recommend Person Who Fit Hearing Aid (Note 2)		15	16	69			4.5	
Repurchase Current Brand Of Hearing Aid (Note 3)		33		67			2.0	
Product Features								
Fit/Comfort	2	6	8	13	80	47	32	10.5
Size	1	6	7	16	77	50	27	11.1
Appearance	1	4	5	13	77	52	25	15.3
Easy Volume Adjustment	3	7	9	16	75	53	26	13.3
Visibility	1	4	6	24	71	47	24	12.6
Packaging	1	2	3	32	64	47	17	19.5
Frequency of Cleaning	2	6	8	29	63	49	16	8.3
Warranty	4	8	12	28	61	43	18	5.0
Ease/Battery Change	4	16	20	21	59	40	19	3.0
On-Going Expense	6	13	18	33	49	35	13	2.7
Performance/Value Factors								
Battery Life	0	4	4	10	86	48	38	21.5
Improves My Hearing	3	8	11	15	74	44	30	8.8
Reliability	3	6	8	20	71	48	23	8.5
Clearness Tone/Sound	5	13	17	24	59	43	17	3.5
Natural Sounding	5	12	17	30	57	39	14	1.1
Value (Price vs. Performance)	8	14	22	28	52	36	14	2.4
Directionality	5	15	20	19	38	38	11	2.4
Whistling/Feedback/Buzzing	8	24	33	30	38	28	19	1.1
Use In Noisy Situations	16	31	47	25	28	21	8	0.6
Listening Environments								
One-On-One	1	3	4	8	88	50	38	22.6
T.V.	3	8	12	19	69	51	12	5.5
Small Groups	3	13	16	21	64	48	15	4.0
Church	5	13	17	29	54	41	14	3.2
Outdoors	4	14	18	29	53	41	12	2.9
Car	5	16	21	28	51	40	12	2.5
Restaurant	7	22	26	29	43	34	9	1.5
Concert/Movie	9	19	28	34	47	33	10	1.5
Telephone	13	23	36	28	36	27	9	1.0
Large Group	14	34	49	27	25	20	5	0.5
Dispenser Service								
Friendliness/Dispenser	0	1	1	7	91	42	19	76.2
Appearance Office	0	1	1	8	91	41	20	39.9
Patient Support	0	1	2	9	89	42	17	19.7
Explained How To Use H.I.	0	2	2	9	89	46	43	37.0
Explained Purpose Hearing Test	0	1	2	10	89	44	44	52.1
Professionalism/Dispenser	0	2	2	10	87	43	35	36.4
Amount Time Spent W/ Consumer	1	2	2	10	87	45	42	38.0
Knowledge/Dispenser	0	2	2	11	87	41	36	41.5
Explained Results Hearing Test	1	2	3	10	87	45	42	33.5
Explained How To Care For H.I.	0	3	3	11	86	46	40	29.7
Explained What to expect from H.I.	1	5	7	14	80	43	36	12.2
Post-Purchase Service	3	5	8	14	79	36	42	10.2

Note: All percents rounded to whole numbers.

Note 1: Dissatisfied=Never, Neutral=Some of the Time, Satisfied=Most of the Time, Very Satisfied=Always

Note 2: Dissatisfied=No, Neutral=Not Sure, Satisfied=Yes

Note 3: Dissatisfied=No, Satisfied=Yes

M E M B E R S H I P

3M Hearing Health
 Argosy Electronics, Inc.
 AudioScience, Inc.
 Bausch & Lomb Hearing Systems Division
 Beltone Electronics Corp.
 Dahlberg, Inc.
 Duracell USA
 Eveready Battery Co.
 Frve Electronics, Inc.

Cennum Corporation
 Hearing Components, Inc.
Hearing Instruments
 Knowles Electronics, Inc.
 Maico Hearing Instruments
 Oticon Inc.
 Personal Sound Technologies, Inc.
 Phonak, Inc.
Phonic Ear Inc
 Precision Acoustics Industries

Qualitone
 Rayovac Corporation
 Resistance Technology, Inc.
 Rexton, Inc.
 Siemens Hearing Instruments
 Starkey Laboratories, Inc.
The Hearing Journal
 Tibbets Industries, Inc.
 Unifon Industries, Inc.
 Widex/HAL-HEN



DEPARTMENT OF HEALTH & HUMAN SERVICES

ATTACHMENT C
Public Health ServiceFood and Drug Administration
1280 Rockville Pike
Rockville MD 20850

AUG 11 1983

Dear Manager of Regulatory Affairs:

As you are no doubt aware, the U.S. Food and Drug Administration ("FDA") issued Warning Letters to six manufacturers of hearing aids because of claims in labeling, promotional literature and advertising. Those letters and this letter, specifically, provide notice to industry that FDA will not permit the use of claims in advertising, promotion or labeling of the devices. Misleading claims include both affirmative representations and omissions of material information.

FDA is concerned about hearing aid manufacturers' performance claims beyond simple amplification of sound. Claims, such as: "make speech more intelligible;" "eliminate background noise;" and "enhance only the sound you want," misleadingly represent similar benefit to all users and require clinical substantiation.

The FDA considers claims of this type to be misleading within the meaning of Sections 502(a) and 502(g) of the Federal Food, Drug and Cosmetic Act ("Act"). Furthermore these claims have not been cleared through the section 510(k) pre-market notification process since they go beyond the intended uses described in 21 CFR 874.3300.

FDA understands that hearing aids have certain technical capabilities and features which can be measured. However, substantiation is required when these technical capabilities are represented to have clinical benefit to users. Manufacturers wishing to make claims relative to user benefit such as in noisy environments must supply clinical data through the 510(k) process.

Labeling, promotional materials, and advertising for these devices should conform to the following principles:

1. Before any performance claim is made it must be substantiated by competent and reliable scientific evidence.
2. Any claims relating to enhanced speech intelligibility, increased understanding in noisy environments, and elimination or reduction of background noise to enhance speech intelligibility, must be supported by clinical data submitted through the 510(k) process.

(over)

Page

2

3. It must be balanced so that the intended audience is informed that these devices will not provide the same benefit to all users; that some hearing impaired persons are not suitable candidates for hearing aids, or hearing aids of certain types; and that, if clearance is obtained under the 510(k) provisions, not all unwanted frequencies are eliminated and some background noise is amplified.

Additionally, users should be informed that benefit may depend on a competent examination, proper fit, and the user's ability to adapt to the hearing aid. Including such balance to promotion and advertising does not, however, eliminate the need for documented substantiation of performance claims.

FDA also recommends that you notify all sales representatives and dispensers of your products, in writing, that oral representations concerning unsubstantiated performance claims may not be made.

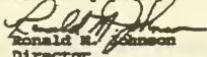
FDA regards this letter as appropriate notice to the industry and many initiate enforcement actions without further notification. These enforcement actions include, but are not limited to seizure, injunction, or civil penalties.

We encourage members of the industry to contact the FDA concerning the status of current promotional materials and to raise any questions about future materials or this letter.

Questions should be addressed to Byron Tart, Acting Director, Promotion and Advertising Policy Staff, Office of Compliance, Center for Devices and Radiological Health (HFD-300), 1350 Piccard Drive, Rockville, Maryland 20850, or by telephone at (301) 435-1342.

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Sincerely yours,


Ronald M. Johnson
Director
Office of Compliance
Center for Devices and
Radiological Health

Senator COHEN. Thank you very much, Ms. Holm.

You indicated in your statement that these issues are old; they've been around a long time, since the 1960's, and that much of the information is anecdotal.

You were in the audience when we had the Deputy Attorney General from West Virginia testify. Would you say that his experience, or his State's experience, with the certain dealer in Charleston was anecdotal or based upon allegations which were substantive enough to proceed against that particular dealer?

Ms. HOLM. Oh, I think it's unfortunate that actions weren't taken even sooner in that particular case.

I believe, West Virginia is an example of a licensing law that is working well. We've been involved in that, and we're pleased with our activities.

Senator COHEN. But you would agree, it's more than anecdotal.

Ms. HOLM. In that case, certainly. But that's only one case, Senator.

Senator COHEN. Well, I understand—

Ms. HOLM. Yes.

Senator COHEN. I have, for example, a letter from a large hearing aid retailer who wrote in response to Vermont's petition for exemption.

The company officials from this national retailer stated the following:

We're concerned about widespread quality problems in the hearing aid industry.

Despite some recent efforts of self-regulation, the hearing aid industry remains plagued with inadequate professional standards, minimal regulation, and a high level of fraud and abuse.

Some States have absolutely no requirements for those entering the field, others require a minimum registration fee or basic examination. But most States have no inspection of facilities or review of the calibration of testing equipment.

No programs relative to quality control exist in any State.

How do you respond to this particular dispenser's statements?

Ms. HOLM. If I understand the question—are you asking me if most States don't have—

Senator COHEN. This retailer is saying some States have no requirements for entering the field, while others have a very minimum requirement.

Ms. HOLM. Well, 46 States have licensing statutes, and I think most of them require a competency examination. Thirty-four require that the licensee demonstrate continuing education before renewal of the license.

I think, most of the States—I'm not sure of the exact number, but most of them require that their equipment be calibrated every year to assure that it is accurate.

Am I answering your—

Senator COHEN. That's fine. That's your statement for the record.

Can I ask you what your feeling is about door-to-door sales or mail order sales? Is that something that your association supports and recommends?

Ms. HOLM. We have a long record with FDA, relative to mail order sales, and also sale of personal amplification devices that are similar to hearing aids, but seem to be evading the FDA regulation. We are opposed in both instances.

We agree with Dr. Kessler. We believe that every hearing impaired American should have a complete comprehensive hearing evaluation prior to the fitting of a hearing aid.

Senator COHEN. Thank you.

Dr. Goldstein, Dr. O'Toole, I'm confused by your statements.

On the one hand, Dr. Goldstein, I think, in a letter to Dr. Kessler, you said, "You should go to a physician first."

And as I understand, Dr. O'Toole, your testimony is that not all physicians are qualified to make the kind of examination that is necessary.

Who do you go to first?

I am a person, let's say, hypothetically, who has a hearing problem. Do I see a physician first, or do I go to an audiologist first?

Dr. GOLDSTEIN. Well, let me say that we feel strongly that at some point before you receive that hearing aid, you should have an exam by a physician knowledgeable in diseases of the ear.

Now, you don't go to a physician necessarily to have the hearing test.

You know, I know a few otolaryngologists who are so compulsive that they wouldn't believe a hearing test unless they did it with their own hands, but most otolaryngologists employ or have some other working arrangement with an audiologist.

I agree completely with Dr. O'Toole's remarks about the training and competency of audiologists to perform sophisticated hearing tests.

I hope he would agree with me that audiologists are not trained to make medical diagnoses or evaluate a patient from a medical point of view.

Senator COHEN. What you're saying is that if you went to the physician, that physician normally would have a trained audiologist that he or she could refer that person to.

What Dr. O'Toole is saying is if you went to the audiologist first, he'd probably refer you back to a physician for an examination.

I think that you made a statement about how cost should not be the driving factor involved in this kind of a decision.

But cost is a driving factor. We're talking about a national health care reform debate that's about to take place, if not today, with the Republican task force's introduction of its measure at least later with President Clinton's on September 22. So cost is a very important factor.

What we have to decide is, who do we go to first? What do we tell the people who are watching out there in the country; what should they do first?

They've got a problem, they see an ad. We know that we should be somewhat skeptical of claims made, and that we ought to go to the professionals and find out do I have a hearing impairment that can be surgically corrected? Is it a tumor, perhaps, that needs to be excised? Is it something less serious than that, but can be corrected by using a hearing device?

What do we recommend to the people?

Dr. O'Toole, you say audiologists first, physicians second.

Dr. Goldstein, I guess, you don't really care, as long as he gets to a physician at some point before the use or purchase of that device.

Dr. GOLDSTEIN. That's correct, sir. Yes.

Dr. O'TOOLE. Senator, the 1977 Food and Drug Administration regulations did list warning signs that trigger immediate referral to a physician. We expect audiologists to take heed of these warning signs.

For example, if the consumer has a history of active drainage from the ear within the past 90 days, or acute or chronic dizziness, or a unilateral hearing loss of sudden or recent onset within the previous 90 days—these are things already outlined in the 1977 Food and Drug Administration regulations. We believe that these warning signs put audiologists on the alert that, indeed, there are situations where the client ought to be referred immediately to a physician specializing in diseases of the ear.

Senator COHEN. Of the 41 States that require audiologists to be licensed, which State do you think has the best licensure law? And what should we look to for a model?

Dr. O'TOOLE. Probably the States of Arkansas and Florida, both have fairly comprehensive laws.

Based on our analysis of 14 audiology laws, which include the dispensing of hearing aids as a legally permissible service, we feel that the statute and rules and regulations of Florida and the rules and regulations of Arkansas are the most descriptive and complete in terms of assurances to consumers of amplification services and products. The other 28 licensure laws for audiologists do not include hearing aid dispensing under the audiology scope of practice and, therefore, licensed audiologists who dispense must obtain a concomitant hearing aid dealer's license and for the most part meet the requirements necessary to obtain that license. This is a significant problem for the audiology community which I submitted previously to the Special Committee.

We also analyzed hearing aid dealers' licensure laws from 49 jurisdictions, including 48 States and the District of Columbia. We believe that the Idaho, and Minnesota statutes are among the most complete and specific laws relative to protections afforded potential consumers of hearing aids. They also contain unique features generally absent from other laws. For example, Idaho specifically delineates the content and requirements of the training program for applicants. Minnesota law imposes a surcharge on licensure fees to fund a consumer education center and requires all hearing aid purchase contracts to be written in plain language.

I would be remiss, however, if I did not point out that licensure laws are only as effective as the enforcement mechanism and resources which support them. This was mentioned in our written testimony and in the report submitted by the AARP, and I would like to reiterate this message: All state hearing aid regulatory bodies need stronger disciplinary powers, and they must have greater personnel and fiscal resources to assist them in enforcement and consumer education.

Senator COHEN. Thank you very much.

Ms. Holm, I don't want to make a major case out of this, but I was struck by your reference to anecdotal evidence, because that suggests that perhaps this is just some people complaining without any substance.

I noticed that in your written testimony, you state that the Boston office of the FDA confirmed a level of 90-percent compliance with FDA regulations in the State of Vermont, after you exclude the records from five dispensers who were charged with consumer fraud.

As I understand it, the FDA only audited 11 facilities, so if you take the five out who were charged with fraud, that's almost half the total of those that they examined.

Ms. HOLM. I thought it was only three—perhaps I'm confused, and I'd like to apologize. I don't want to minimize the importance of consumer complaints.

I guess, we were focusing more on the AARP report. They described their report as being anecdotal in nature. I apologize.

Senator COHEN. Well, thank you all very much. What we have tried to demonstrate, or at least extract out of this hearing, is the fact that there's a major problem with hearing loss. That as we're growing older and living longer, more and more people are going to need assistance. That all of us want to see to it that the devices that are marketed to the American consumer, measure up to the claims that are made by the manufacturer and/or distributor of that device. That those people who are employed in the dispensing of the equipment itself, are well-trained and do not engage in the kind of abusive sales tactics that are directed toward a more vulnerable segment of our society, or are allowed to go unchecked. And that there be an opportunity for consumers to have their rights protected through various State licensing boards, and enforcement and oversight.

That really is the objective, and whether we go to a physician first, and an audiologist second, or to the audiologist first, and the physician second, I think it has become clear to me that what we want to do is discourage abusive forms of over-the-counter, mail order, or door-to-door sales techniques.

This is a serious piece of medical equipment, and it's expensive. Hopefully, it will enhance the quality of life for millions of people, and we are here to see to it that we get the best product for the best price for the general population that's in need of it.

Your testimonies have been very helpful today, and hopefully, we'll begin the process of educating the American people about what is necessary.

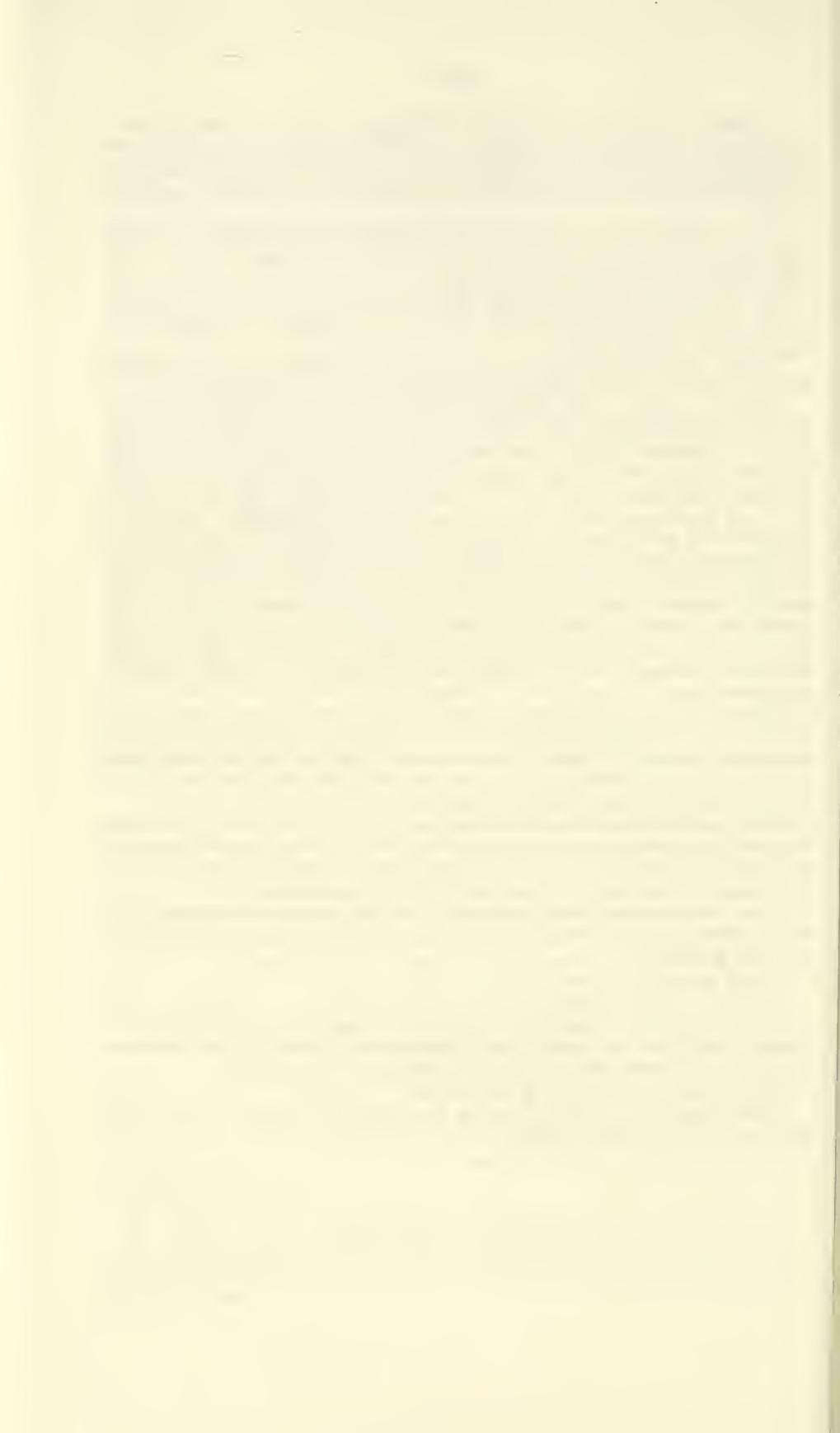
Thank you all.

Ms. HOLM. Thank you.

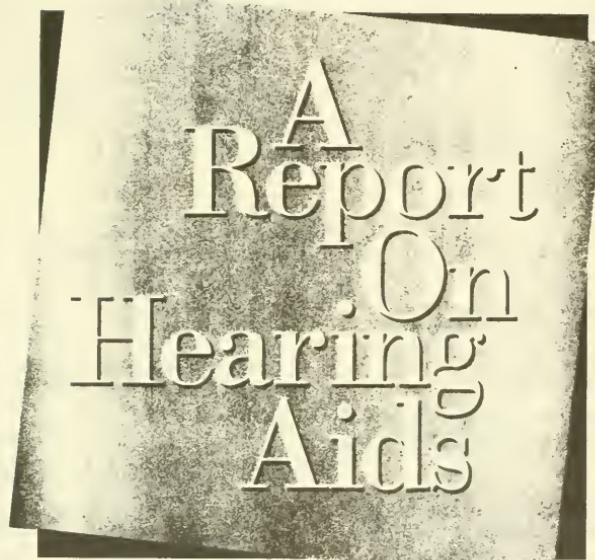
Senator COHEN. I particularly want to thank our witnesses who travelled all the way from West Virginia to be here. It's very important that you were here, and we appreciate it very much.

The Committee will stand adjourned.

[Whereupon, at 12:40 p.m., the Committee adjourned, to reconvene at the call of the Chair.]



A P P E N D I X 1



User Perspectives and Concerns

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Acknowledgements

The Consumer Affairs Section wishes to thank the following persons for their help in bringing this report to completion: The eight thousand AARP members who patiently wrote sharing their experiences with this important product; Volunteer testers in Tampa and West Palm Beach, FL who spent several months visiting hearing aid sellers; Lawrence Breeden, Director, and the West Palm Beach Division of Consumer Affairs for their timely assistance; Pat Powers of the University of Maryland's School of Social Work for her valuable comments; and many others who contributed to this report.

AARP Consumer Affairs Section

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Introduction and Summary

This report summarizes an investigative study of the hearing aid marketplace by the Consumer Affairs Section of the American Association of Retired Persons.¹ It reviews more than 18 months of consumer-oriented research about users, manufacturers, and sellers.

The mission of Consumer Affairs is to promote a fair and effective marketplace for older consumers. This report is one in a series of investigative projects looking at the consumer goods and services marketed primarily to that audience.

This report indicates that millions more people should be wearing hearing aids for social and safety reasons. The Association encourages the use of hearing aids by all consumers who need them. But this study also seeks to ask fundamental consumer questions about the product. Questions that are routinely asked about other consumer purchases.

It seeks to:

- Identify and help correct consumer problems.
- Increase awareness of the problems surrounding certain products.
- Provide consumers with useful information about products.
- Provide background information to consumer protection officials.
- Initiate policy discussions about the regulation of these products.

This report is anecdotal in nature. It is based upon users who wrote to AARP or testers who volunteered to shop for an aid. It is information from a self-selected group of people and therefore, the data are not generalizable to the population as a whole. Nonetheless, the issues raised by 4,000 users and the consumer tester experience reported here should not be minimized.

Hearing aids are a major consumer issue for older persons. They are the primary users of these products and they are also the largest segment of the estimated 23.5 million people with a hearing loss.

A hearing aid, costing more than an average of \$600 per aid, is often among the most expensive purchases made by an older adult. About half of all users employ not just one, but two aids. Most consumers pay for these products out of their own pocket. Neither Medicare nor most health insurance plans pay for hearing tests or hearing aids, except under very limited circumstances.

Purchasing an aid can be a confusing process, particularly for first-time buyers. The list of manufacturers, providers, and regulators can be baffling. How can the consumer compare hundreds of different models and many different technologies?

¹ AARP is associated with hearing aids in four ways. First, the Association publishes consumer publications on hearing and hearing aids.

Second, AARP has adopted a number of policy positions regarding this product.

Third, the Association's advertising standards permit generic hearing aid advertising in its publications. Product-specific ads are not accepted.

Finally, the AARP Pharmacy Service leases space in three of its pharmacies to a provider who evaluates and fits hearing aids. Sales in 1992 were significantly less than one half of one percent of the hearing aid market.

The buyer must rely on the seller to make comparisons, but there are different types of occupations that test hearing and fit aids. Should you contact your family physician first? Does he/she know anything about hearing loss or hearing aids? What about an ear specialist? An audiologist? A hearing aid specialist? Are they competent? Do they follow proper procedures? How do I know?

While every buyer must answer these questions individually, this report provides information about users, products, and sales.² It focuses on three major areas: (1) background about the marketplace; (2) detailed consumer responses to questions about the product; and, (3) the results of a consumer shopping study.

The findings include:

Background -- Approximately 20 million people who need a hearing aid, don't wear one. Hearing aid sales in 1992 were 1.78 million. According to a professional journal, hearing aid growth is "stagnant." (see p.11)

There are three distinct occupations that serve people with hearing loss and sell hearing aids. These are physicians, audiologists, and hearing specialists.

The manufacturing and sale of hearing aids are regulated at both the federal and state level, but enforcement actions are minimal. Until the Food and Drug Administration's (FDA) April 1993 ban on what it called misleading and confusing advertising claims, there had been almost no regulatory activity at the federal level.

Consumer Responses -- Consumer satisfaction with hearing aids generally appears to be low. An industry survey reported a satisfaction level of 58 percent in 1991, up from 55 percent (see p.30). This is far less than a 1985 study commissioned by the Federal Trade Commission which reported an 84 percent satisfaction rate. This finding was used to justify the termination of a federal rulemaking proceeding. However, satisfaction is below 50 percent in the 4,000 letters from AARP hearing aid users. It is these letters that are the basis of this analysis.

Based on letters to AARP, consumer reactions and hearing aid prices varied considerably from brand to brand. Users seem to be more satisfied with sellers than manufacturers.

Shopping Experience Study -- The hearing aid seller may not be where consumers should place their trust, however. Older consumer testers visited 23 hearing aid sales operations in two cities in Florida in the summer and fall of 1992. Many sellers failed to follow the minimum testing standards mandated by the state. A number of retail operations evaluated hearing in what consumer testers considered noisy rooms. If a subject is distracted by extraneous noise while being evaluated, this can change the results and is a violation of state regulations.

Contrary to federal regulations, one seller told a consumer tester that it was not in his "best interest" to see a physician before purchasing an aid. Another said a hearing aid would "exercise the nerve and slow down the hearing loss." And still another said a 30-day trial period wasn't necessary because 24K gold circuits were used throughout the hearing aid.

² Most of this research was conducted under contract to the Association by the Institute for Technology Development (ITD). This is a private, non-profit research firm that focuses on consumer products and the older population. The principal researcher for this project was Margaret Hyde, a certified Ph.D. audiologist.

The central theme of this report is not about major new federal legislation and/or trade regulations. The thesis is that the very nature of hearing loss, the complexity of hearing instruments, and number of hearing occupations involved in this industry creates an atmosphere for consumer problems and the need for continuing oversight. That oversight has been wanting for years.

Certainly policy reforms are needed, particularly at the state level. Competency standards must be improved, minimum standards of practice must be established, and a trial period should be standard in all 50 states. Many states don't have one or more of these items.

However, there are many workable statutes and regulations at the federal and state levels. The question is why isn't more done with what's already on the books? Why aren't regulators proactive? Has the era of benign neglect for this market come to an end?

We applaud the recent action by the FDA to ban misleading advertising, require documentation for any claims, and Commissioner David Kessler's call for "stringent new standards that will change the way hearing aids are sold." This is a dramatic change. Hopefully, it is a signal of a new era.

Comments

A draft copy of this report was sent to manufacturers, trade and occupational associations, federal and state regulators, and consumer groups. A total of 25 draft copies were mailed out.

The breadth of the comments on the draft was quite striking. They ranged from the following:

*Robin Holm, Executive Director, International Hearing Society.
"We do not believe the report, as currently drafted, is fair, valid,
or accurate...the drafters determined to write a report
which...seeks to justify mandatory hearing evaluations by
clinical audiologists. AARP's involvement in this self-evident
professional turf battle is distressing..."*

*Martie Ormsby, President, GN Denavox, Inc.
"I applaud you...for what I consider to be a fair comprehensive
and insightful report. Though I find many of its findings
distressing, I am not surprised by them."*

Many of the suggestions received were wholly or partially adopted. Others are referenced in a footnote. Some suggestions were rejected. At the end of each chapter, a special section summarizes significant viewpoints that weren't incorporated.

Chapter One

Background

"I tell you I am never without them (hearing aids).
The first day I wore them out of the office I heard the
birds singing. How long had I not heard them?"

Letter to AARP

The hearing aid market is both diverse and confusing to consumers and regulators alike. This chapter reviews background information to enable the reader to better understand the findings in Chapters Two and Three.

- Hearing aids are the third most widely used assistive device, following glasses and canes.
- Hearing aids are an older persons' consumer issue. Older adults purchase almost 65 percent of all aids.
- Hearing loss affects 23.5 million Americans, 60 percent of whom are over the age of 65.
- Only about 22 percent of the population with a hearing loss wears a hearing instrument.
- The average retail price of an aid is \$600 or more.
- Neither Medicare nor most health insurance policies pay for hearing aids.

This Chapter is an introduction to the consumer purchase of the medical device called a hearing aid. To better understand the research outlined in Chapters two and three, it's useful to review some facts about the market. This chapter includes sections on:

- Hearing loss
- Hearing aid users
- Hearing aids
- Manufacturers
- Sales network, and
- Regulatory activity.

The Nature of Hearing Loss

Hearing loss or the inability to hear certain frequencies of sound, affects 23.5 million Americans most of whom are 65 and older. The loss could be mild, moderate, severe, or profound as measured in decibels of sound. A hearing loss is too often accepted as another part of the aging process: "I hear as well as can be expected for my age."

A hearing loss is more accurately described as an accumulation of many years of trauma to the ear. This trauma can be caused by loud noises (recreational equipment, machinery, loud music, and so on); medications, cigarette smoke, air pollution, and illnesses that can attack the inner ear (influenza, mumps, etc.).

A hearing loss is invisible and can be dangerous. In the beginning, it may be almost unnoticed and increases only gradually. It may be unrecognized for years. Most adults have a sensorineural loss, sometimes called nerve deafness, that cannot be treated medically.

A hearing loss can alter the reception of sound so that clarity or the ability to distinguish between sounds is lost. For instance, the ability to hear higher frequencies (pitches) may be diminished or muffled. Background noise may then become a major problem. The person with a hearing loss may say, "I can hear you but I can't understand you."

Some consumers unconsciously develop compensating mechanisms to cope. For example, they rely on visual clues such as reading lips or gestures. Others cannot compensate and find themselves cut out of even the most basic communications of everyday living.

"If I wanted to hear what a woman said...I would have to bend over and put my ear practically in her mouth... I also had the feeling that I was getting that 'dumb look' standing in a group when I couldn't hear."

Former Surgeon General
C. Everett Koop

For most of those with a hearing loss, an amplification device called a hearing aid improves their hearing dramatically. Dr. Koop, for instance, now wears two aids and can "stand upright, talk to people, hear them, and make appropriate responses." Without an aid, those with a hearing loss could bring danger to themselves and others. For example, in focus groups sponsored by the hearing aid manufacturers association (Hearing Industries Association or HIA), one person with a hearing loss disclosed she drives her car with the windows open year round. That's the only way she can hear the traffic noise.

Hearing Aid Users

However, more than three-fourths of those who need amplification, don't use an aid. There are an estimated 23.5 million people with a hearing loss (Kochkin, 1991). However, only 3.78¹ million people own one or two aids (Advance Data, U.S. Department of Health and Human Services, 1992). That is a gap of almost 20 million people. More than half of these acknowledge their hearing loss but have decided not to buy an aid (Christy, 1991).

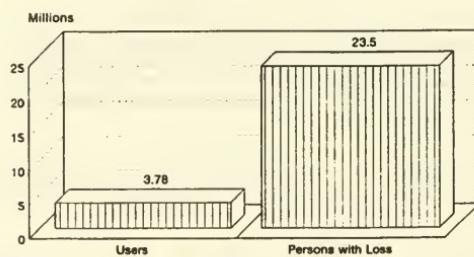
Reasons for not wearing an aid include:

- A perception that the loss is not severe enough.
- The cost of aids is too high.
- Perceived negative images associated with wearing an aid.
- Problems with the product such as background noise, maintenance expenses, and a "hassle" to use.

(Kochkin, 1993).

Figure 1

Hearing Aid Users and Persons with Hearing Loss



Sources: U.S. Dept of HHS and Kochkin (1991)

Without a doubt, persons with a hearing impairment are well served by wearing an aid. In one recent survey, 65 percent of users indicated that hearing instruments have improved their life. Eight out of ten owners would also recommend a hearing aid to a friend (Kochkin, 1993).

¹ Industry studies indicate there are almost six million users.

As our world becomes more sophisticated, it is impossible to develop consumer competency with all purchases. This is particularly true with medical devices. The consumer presumes the practitioner knows everything. So too with hearing aids. Most consumers and particularly first time buyers are at the mercy of the seller.

For older consumers, the problem is even more complex. Older consumers are considered to be a vulnerable population. Research by social scientists has found that people over 65 years of age tend to be:

- More trusting
 - Less likely to recognize bad buying experiences
 - Less knowledgeable about their rights as consumers and,
 - Less likely to complain.
- (*Older Consumer Behavior*, AARP, 1990 and Hunt, 1991.)

These factors further complicate the hearing aid purchase for users and can lead to consumer abuses.

What is a Hearing Aid

A hearing aid is an electronic device that picks up sound waves with a microphone, amplifies the sound, and conveys it to the ear through a tiny speaker. A small battery powers the instrument. The sound amplified by an aid should be tailored to the user's hearing loss. Almost all hearing aids sold today are called behind-the-ear, in-the-ear, or in-the-[ear] canal products.

While hearing aids are frequently compared to eyeglasses, in truth there is little similarity. Eyeglasses almost always bring vision back to 20/20 for the wearer. An aid, however, cannot bring hearing back to the equivalent of "20/20" in hearing.

Most of the sounds needed to understand speech are in the 250 to 8,000 Hz (Hertz or cycles per second) range. Most distracting background noise is between 100 and 500 Hz. A hearing aid doesn't distinguish between background noise (the sound you don't want to hear such as an air conditioner) and the sound you do want to hear (a child talking). Both may be amplified and the resulting din may make it hard to differentiate between the different sounds.

Some hearing aids amplify frequencies above 1000 Hz more than those below. These aids do help some wearers distinguish between sounds in a noisy environment. To date however, the ability to distinguish between sounds is improved but not solved. Background noise remains a persistent problem for manufacturers and users alike. It is the focus of substantial industry and university research.

Background noise is also the subject of much of what the FDA called "misleading" advertising.

Hearing Aid Manufacturers

In 1992, 42 hearing aid manufacturers sold an estimated 1.78 million hearing aids (Kirkwood, 1992).² Most manufacturers wholesale their wares to sellers retailing several different brands of aids. Two major manufacturers with about 20 percent of the market, Beltone and Dahlberg, which manufacturers Miracle-Ear, market their hearing aids through exclusive dispenser agreements or franchise operations.

² This figure includes aids exported to other countries.

Most manufacturers don't build their aids from the "ground up." Rather, they purchase certain components (microphones, receivers, and amplifiers) from among a few suppliers. For example, Knowles Electronics makes most of the microphones and speakers (transducers) used by all manufacturers. Some components and circuits are custom made for a particular manufacturer.³

Some companies build hearing aids under more than one brand name. Dahlberg also owns Audiotone and Starkey owns Omni, for example. At least one manufacturer, Oticon, sold hearing aids to another manufacturer for use under that company's name.

Manufacturers produce stock models that have a variety of settings and options, as well as "custom built" hearing aids. Hearing aid components and circuitry are continually being changed as are the technologies for fitting aids. The hearing aid seller must now have special instrumentation to be able to offer the newest products to the consumer. In the opinion of many hearing professionals, hearing aid technology and products have improved significantly in the last ten years.

Hearing aid sales, according to a professional journal, are "stagnant" (*Audiology Today*, 1993). Actual unit sales have increased, but market penetration has not. Between 1984 and 1990, unit sales increased by almost half a million, 1,110,926 to 1,590,999 (Kirkwood, 1992).

The penetration rate, however, (hearing aid owners compared to the hearing impaired population), has remained almost constant. In 1984 it was 23.7 percent and in 1990, it declined to 22.3 percent (*Audiology Today*, 1993).

The number of professionals dispensing aids has doubled since 1978. In 1990 there were more than 11,000 professionals dispensing an average of 124 aids each (Cranmer, 1991).

All manufacturers have some form of "return policy" whereby sellers can return an aid for credit within 30 to 90 days. This liberal return policy is unique to this industry. Consumers can also benefit from this policy. They can, in many instances, return an unsatisfactory aid within 30 days and pay only a small fee to the seller. State law mandates at least a 30-day return policy in more than 20 states. This policy eliminates some of the risk in buying an aid. It is also a tacit acknowledgement of the complexity of the purchase and the possibility that a selected aid may not work for everyone.

In 1992, 16 out of every 100 aids sold were returned to the manufacturer for credit (Kirkwood, 1993).⁴ The primary reason for a high return rate was that the aid was not providing sufficient benefit (Madell, Pfeffer, Ross, and Chellappa, 1991). Consumers also reported discomfort, problems in noisy surroundings, and other reasons. Inexperienced users rejected aids more often than experienced users; older inexperienced users rejected them more frequently than younger inexperienced users.

As a number of reviewers indicated, a return rate of 16 percent does not mean a rejection of hearing aids. The consumer may return one aid only to select a different product or try two products simultaneously. One researcher estimates that the return rates among consumers is around 5 percent (Cranmer, 1991).

³ A number of reviewers objected to the reference that "most hearing aid manufacturers don't build their aids from the ground up..." John Zei, President of Siemens, wrote, "It is time to put this old canard to rest. Manufacturers do more than simply 'assemble' hearing aids."

In a series of interviews conducted by Dr. Wylde in 1991, a number of manufacturers were asked about this issue. What they said relates to the statement about building aids from the ground up. Those interviewed were promised anonymity.

One manufacturer stated, "We are like everybody else...we buy from Knowles like everybody else and make just about everything else." Another stated, "Everybody buys components from outside. None of us make the circuits themselves...If you ask most of the companies, they will say the same thing."

⁴ During the fourth quarter of 1992, it rose to 17.3 percent.

Most manufacturers don't advertise their wares to the general public. Instead, they advance their products to sellers in trade publications and trade shows. The major exceptions to this policy are Miracle-Ear and Beltone which widely advertise their products on television, radio, and in print.

The Sales Network

There are three occupational groupings serving people with hearing impairment and selling aids. Members of all three claim expertise in evaluating hearing and fitting aids. To the average consumer, however, the different titles and credentials are confusing (HIA, Focus Group Research, 1990). Similarly, buyers may be ill-equipped to distinguish between good practice and bad.

The three occupations are:

- **Hearing instrument specialists** -- sometimes called hearing aid dealers, hearing aid specialists, hearing aid fitters, and other titles. It's difficult to make generic statements about this occupation since the licensing requirements of 48 different states vary substantially, but generally a specialist must:
 - 1) Be a high-school graduate or have a GED.
 - 2) Be 18 years or older.
 - 3) Be in good health and of good moral character.
 - 4) Complete a limited training program (in some states).
 - 5) Pass a written licensure examination which may include a practical component (at least 40 states require a written examination and 37 mandate some combination of a practical and oral examination [Lewis and Powers, 1992]).

Specialists usually work in retail sales establishments that only test hearing and sell aids. Cranmer-Briskey (1992) reported there were 5,000 hearing specialists in business in 1991. They sell about half of all hearing aids sold.

- **Audiologists** -- persons involved in fitting aids and providing aural rehabilitation. They are usually certified by the American Speech - Language - Hearing Association (ASHA), a professional membership association. The credential is called a Certificate on Clinical Competence or CCC-A.

To be certified, the candidate must:

- 1) Complete at least a master's degree in audiology, the science of hearing defects and treatment.
- 2) Complete a nine-month, post-graduate clinical internship.
- 3) Pass a national examination in audiology.

There are 2,100 audiologists in private practice dispensing aids, and 2,900 dispensing in clinics (Cranmer-Briskey, 1992).

- **Physicians** -- those who are primarily involved in diagnosing and treating the ear. Historically, physicians didn't dispense aids. However, the number who do is increasing. Physicians sell hearing aids through their offices. Many of these have audiologists on staff. There are three medical specialists. These are:

Otolologist -- a specialist in treating the ear.
 Otorhinolaryngologist -- a specialist in treating the ear, nose, and throat.
 Otolaryngologist -- a specialist in treating the ear and throat.

Regulators

Federal Level -- Two separate federal agencies have overlapping authority over the hearing aid marketplace. These are the **Federal Trade Commission (FTC)** and the **Food and Drug Administration (FDA)**.

FTC -- The agency with the broadest authority is the FTC. It regulates both advertising and sales practices under its standard deceptive claims and practices jurisdiction.

In fact, the FTC has a long history of regulatory actions pertaining to the manufacture and sale of these products. The Commission secured its first order prohibiting false advertising by a hearing aid manufacturer in 1934. Between 1934 and 1976, the FTC obtained orders, consent decrees, or voluntary compliance actions in 66 cases against both manufacturers and sellers.

In 1975, the FTC initiated hearings to develop a Trade Rule for the hearing aid industry. A Trade Rule spells out certain practices which the FTC considers to be deceptive. A Rule makes enforcement more consistent, especially when there's a national market for the product and there are a number of enforcement and regulatory agencies.

Commission staff argued that case-by-case litigation with this industry was ineffective. Case-by-case litigation failed to provide the broad public notice needed to inform consumers at large. The history of litigation showed both sellers and manufacturers as repeat offenders involved in multiple cases. Cracking down on repeat offenders is less likely to benefit unknowing buyers than a broad Trade Rule.

Consider that in 1976 the FTC signed Consent Orders with six manufacturers.⁵ Without admitting guilt, these companies agreed to cease misrepresenting the "benefits, characteristics, efficacy, and uniqueness" of their products. Yet prior to these consent decrees, the FTC already had two orders against Beltone, two orders and two assurances of voluntary compliance with Dahlberg, one order and one voluntary compliance with Maico, one order against Qualitone, and two orders and two assurances of voluntary compliance with Sonotone. The sixth firm was not previously cited.

The agency's proposed Hearing Aid Trade Rule (Proposed Trade Regulation Rule, 40 Fed. Reg. 26646, 26652 [1975]) would have imposed comprehensive requirements on both manufacturers and sellers including:

- A 30-day free trial period
- A requirement that retailers disclose their status as sellers, and,
- A prohibition against deceptive claims.

In 1982 Commission staff narrowed the proposal on the basis of evidence accumulated during lengthy hearings. The Commission had also rejected the broader rule and adopted new evidentiary standards. The proposed Rule became a single item: consumers were to be guaranteed a 30-day free trial period. According to a staff report, "Only the trial use of the selected aid in a representative variety of actual listening situations can remove the...risk that no significant benefit will be received." (Proposed Trade Regulation for the Hearing Aid Industry, Federal Trade Commission Staff Report, 1985).

In 1985, the full Commission voted four to one to drop the proposed Rule and terminate the Rulemaking proceeding. Their vote was premised upon a survey of hearing aid purchasers conducted in 1984 by Market Facts, a polling firm. The FTC's Bureau of Consumer Protection had commissioned the study and reported:

- "The overwhelming majority (84 percent) of hearing aid buyers are [were] satisfied with their purchases, and,
- In "at least 70 percent of sales taking place within a year before the survey," a trial period was offered (FTC News Release, 1985).

Based on this information, then FTC Chairman Miller argued, "the recent survey results, together with other evidence warrants a conclusion that the evidence in the record does not support a rule" (Statement of Chairman Miller Concerning Hearing Aid Rulemaking, September 16, 1985).

⁵ Beltone Electronics Corporation, 88 F.T.C. 336 (1976); Dahlberg Electronics, Inc., 88 F.T.C. 319 (1976); Maico Hearing Instruments, Inc., 88 F.T.C. 298 (1976); Qualitone, Inc., 88 F.T.C. 287 (1976); Radioear Corporation, 88 F.T.C. 308 (1976); Sonotone Corporation, 88 F.T.C. 368 (1976).

Both AARP and ASHA, as consumer representatives, challenged these findings and appealed to the commission to leave the record open. Both offered to conduct additional surveys. The Commission rejected this proposal and closed the proceeding.

Although the Commission dropped the rulemaking, it decided to return to case-by-case enforcement as appropriate. The FTC's authority to pursue case-by-case litigation had in fact, been broadened. Congress added civil penalties for violations. That is, when a party has notice that the Commission has adjudicated a practice as unfair or deceptive and engages in the practice again, it may be liable for civil penalties (15 U.S.C. Section 57(b) as amended by Pub. L. 93-637, Title II, Section 206(e), 88 Stat 2201 [1975]).

Even though the FTC's authority is broad, it has taken almost no action since 1985. Between 1985 and 1993, the FTC reported action in only two cases, both were sellers.⁶

Consumer complaints however, have not gone away (see below, and see Chapters two and three of this report). Advertising claims, for example, are a major issue, but the FTC has been on the sidelines to date.

It does have an open investigation regarding Miracle-Ear and possibly, others. In its own news release dated May 10, 1993, Dahlberg indicates it is in compliance with the 1976 consent decree with the FTC (see above). It also went on to say the FTC's enforcement division has proposed that Dahlberg:

- Substantiate advertising claims.
- Extend its 90-day refund policy to consumers.
- Make certain disclosures in its advertising.
- Pay a civil penalty.

FDA -- This agency has nominally regulated hearing aids as medical devices since 1977. Its primary focus is the safety and effectiveness of the device. Nonetheless, FDA's regulations include labeling requirements and protections in the sale of aids to first-time buyers. (See 21 C.F.R. Section 801.420 et seq.).

While the FDA has broad authority, the agency focused minimal attention on hearing aids until 1993. Because of limited resources, the agency set its priorities on critical devices like heart valves, pacemakers, and so on. Hearing aids are not "an inherently dangerous device," according to the FDA. (42 Fed Reg 31, 9288, 1977). Therefore they weren't on the agency's priority list. It was hearing aid advertising that turned that agency around.

"In 1990, I heard all the wonderful commercials and thought I would go for it. It was decided I needed two hearing aids at total cost of \$1550.

I am really disappointed and feel...[these] aids are not any better than previous aids and highly exaggerated in their advertisements."

Letter to AARP

Objections to hearing aid ads are widespread among professionals. For example, John Zeigler, an audiologist in Florida wrote a scathing letter to the *Hearing Journal*, a trade publication, in late 1992. According to Zeigler, Miracle-Ear's claim of moving unwanted noise into the background, "creates unrealistic expectations. No hearing aid in the world [only] picks up the sounds people want to hear." Later he asked, "Do we have to deliver misinformation to sell hearing aids?"

⁶ In February of 1991, the FTC filed suit against Doro Lee Inc., (dba Brown Hearing Centers of Orange, TX). The complaint charged Doro Lee with violating the Commission's "Door-to-Door" Sales Rule in marketing hearing aids in homes (FTC News Release, 1991).

In March of 1993 the FTC signed consent decrees with seven hearing aid retailers in California, New York, and Massachusetts. According to the FTC, these firms allegedly placed ads for hearing aids in various Yellow Pages directories using the term "Medicare," the federal health care program for people over 65. The term was used in such a way that it appeared to imply that Medicare would pay for the cost of hearing aids, hearing tests, or both (FTC News Release, 1993). Medicare does not cover hearing aids and only pays for hearing tests when ordered by a physician to diagnose a medical problem.

Zeigler's letter launched a furor. After many more letters, the *Hearing Journal* editorialized that it had received a loud and clear message of agreement with Zeigler's comments. David Kirkwood, the editor, wrote, "we share...the concern that the Miracle-Ear ad promises more than it...can deliver." Curiously, however, there was no call for withdrawing the ads. Kirkwood placed the responsibility for correcting the problem with the dispenser. He wrote, "the dispenser has an opportunity -- and an obligation -- to set him [the customer] straight."

David Kessler, the Commissioner of the FDA, also felt these ads raised questions and launched an investigation in late 1992. In April of 1993, the FDA changed directions. It issued warning letters to six hearing aid manufacturers: Beltone, Dahlberg, Electone, Omni, Siemens, and Starkey (Letters to Manufacturers, 1993). The director of the FDA's Office of Compliance for the Center for Devices and Radiological Health charged them with making "misleading claims to consumers" through advertising, promotional literature, and labels.

All of the allegedly misleading claims related to speech recognition and background noise. For example, the FDA specifically referred to the following advertising claims:

"ClearVoice's sophisticated noise reduction system suppresses annoying background sounds and helps you hear voices clearly even in crowded places."

(Beltone)

"The Clarifier. The hearing aid that automatically reduces background noise...even in noisy situations."

(Miracle-Ear)

"Digital Word Processor hearing instrument will bring back many of the sounds you have been missing and you will learn to 'focus in' on what you desire to hear while placing unwanted noise in the background."

(Starkey)

(FDA Letters to Manufacturers, 1993)

The FDA charged each manufacturer with:

- Misleading claims that imply users will be able to distinguish speech from undesirable noises.
- Performance claims that haven't been substantiated with clinical data.
- Claims that aren't balanced and that fail to disclose material information.
- Claims that overstate the quality and value of the aids.

The letters advised manufacturers to remove their current literature and advertising immediately or face "regulatory actions." In addition, each company is to "correct misconceptions about its hearing aids" and to provide documentation for any future advertising claims.

As this is written, all the manufacturers agreed to withdraw their ads. It is unclear, however, how the industry will respond to the issue of clinical trials for future claims.

State Level -- Federal regulations generally don't extend to the level of testing and fitting of individual consumers. Professional competency and consumer protection in hearing aid sales are regulated principally at the state level.

Licensing Boards -- Historically, states developed a system of professional licensing for many occupations including hearing instrument specialists, audiologists, and physicians. States first licensed physicians in the 19th century, but most hearing instrument specialist boards are relatively new. They date back to the 1960s (Lewis and Povers, 1992). Audiology boards are also relatively new with the first state licensing law enacted in 1969.

Licensing boards normally consist of professional and consumer members. The number of consumer or public members varies from state to state and in a number of states, there are no public members. These boards set standards for minimum competency, licensure, and practice; investigate complaints; and discipline practitioners. There is considerable variation in requirements between states and between occupations.

Hearing instrument specialists -- State boards license this occupation in almost all states (a few states merely register specialists). Massachusetts and Colorado don't regulate hearing aid specialists at all.

Audiologists -- Forty-three states regulate audiologists through their own licensing boards. State licensure requirements normally demand ASHA (CCC-A) certification. In some states, audiologists dispensing aids must also be licensed as hearing aid specialists.

Physicians -- Physicians are licensed by medical licensing boards and certified in their specialty by professional organizations (colleges). Frequently, dispensing physicians are "grandfathered in" as hearing specialists under state law or regulations.

According to a recent consumer survey of hearing instrument specialist boards, "Most boards have adequate oversight, disciplinary, and enforcement powers, but seldom use them."⁷ For a three year time period (1988-1990), ten boards took no disciplinary action and 12 others were only "minimally active." In 1990, 37 state specialist boards took a total of 136 disciplinary actions (Lewis and Powers, 1992).

Few boards are proactive because they have insufficient staff to monitor sales activity. The investigator for New Mexico's board, for example, serves 11 other licensing boards. Hearing instrument specialist boards are primarily reactive, responding to consumer complaints.

Attorneys General -- In addition to state licensing boards, the 50 state attorneys general also have broad authority. Many serve as legal counsel to licensing boards. All of them have authority over state consumer protection statutes. Some attorneys general, e.g., Vermont and Minnesota, have been proactive in hearing aid sales seeking stricter regulation and enforcement.

For example, Vermont's attorney general successfully pushed state regulation of hearing aid sellers in that state. He argued that dispensers among other things, were:

- Prescribing unnecessary aids
- Using deceptive advertising
- Failing to provide mandated refunds
- Charging excessive prices, and,
- Providing inadequate contract disclosures.

Others have investigated complaints of false advertising, return policies, and additional consumer abuses.

Perhaps, because of the complexity of this transaction, attorneys general have not been as involved as in other areas of consumer protection.

Conclusion

While both federal and state regulators have extensive authority to oversee the manufacture and sale of this product, there has been a lengthy period of benign neglect in consumer protection activities. Only in the last few months have federal and state agencies taken major steps to clamp down on misleading claims and practices.

Comments

Michael Hoke, Argosy Electronics, Inc.

It is important to note that [the large number of models and circuits] gives the consumer...a benefit. Limiting choices is generally bad for consumers."

Carole Rogin, president, Hearing Industries Association.

"We would suggest that the current regulation of hearing aids is appropriate and should be adhered to and enforced. Additionally, I would observe that many of the concerns that the report outlines...may be more appropriately addressed through consumer education and information..."

Lawrence Posen, president, Beltone Electronics Corporation.
"Clear product performance standards (ANSI Standards) exist and are checked. All hearing aid producers comply with the FDA's "Good Manufacturing Practices" regulations. Most states have strong regulations on the books and extensive authority to oversee sales practices."

⁷ No similar study of audiological boards exists.

Chapter Two

Consumer Response

Chapter Two looks at AARP member/user responses from across the country. These responses were collected from two sources -- 4,000 letters and a follow-up questionnaire sent to 1,000 of the original letter writers.

- I). Four thousand users wrote AARP in response to a newspaper article (see Appendix). These letters were analyzed and tabulated.
 - 43 percent of the letter writers made only positive statements about their aid and 34 percent made only negative statements.
 - 66 percent wear their aid(s) all day long.
 - Only one manufacturer sold more than 15 percent of the aids purchased by the 4,000 letter writers.
 - 23 percent complained about background noise with their aids.

- II). To gather additional information and to confirm the findings of the letter writers' analysis, a follow-up questionnaire was mailed. A 25 question instrument was mailed to 1000 of the previous letter writers. The response rate was 86 percent.
 - 30 percent indicated they were college graduates.
 - "Word of mouth" was the reason 35 percent gave for visiting a particular sales agency. Advertising was cited by 20 percent.
 - 50 percent of the respondents were satisfied with their aid but 79 percent were satisfied with the seller.
 - Hearing aid sales prices varied from \$150 to \$1800 for a single aid. The average price was \$660.

This chapter looks at user response collected from 4,000 users and through a questionnaire. It discusses positives and negatives about the product based on communication with a large group of users.

This combination of letters and the responses to the questionnaire is probably one of the largest collections of user opinion on hearing aids collected to date. It must be carefully assessed, however. Users self-selected themselves by writing to AARP in response to a newspaper article (see below). Therefore, their responses are not generalizable to either hearing aid users or the older population as a whole.

Nonetheless, the issues raised by these users should not be minimized. First, consumers defined the issues that concerned them. Second, the letter writers appear to be both long-time and full-time users, with higher education levels than the older population as a whole. In short, these are the repeat customers that sellers need to reach. Third, while these letters include people with complaints, more than 1,700 writers had nothing but positive things to say about the benefits of wearing their aids. Finally, some of the data is similar to other hearing aid research.

Part One, Letters -- Part one of this chapter summarizes 4,000 letters written by hearing aid users. In September 1991, AARP's Bulletin, the Association's monthly newspaper sent to all members, published a small article directed at hearing aid users (see appendix). They were asked to write and share their experiences with the product by answering five questions:

- Brand name of the aid
- Date of purchase
- Price paid for one or two aids
- Where the aid was purchased
- What their experience was.

Half of the letters¹ received were tabulated and analyzed. Almost every writer answered the five questions listed above. But they also provided much more. Some included photocopies of invoices. Others provided pages of description about themselves and their aid. Many writers told AARP how they've learned to cope with a hearing loss and offered advice for first time buyers.

Researchers at the Institute for Technology Development (ITD), under contract to AARP, tabulated the answers to the five questions and categorized the additional information. Not every letter writer addressed each issue analyzed here. Therefore, for clarity, each chart or table in Part One will indicate the number of people writing about that topic. For example, N = 3,530 means 3,530 people addressed that issue.

Part Two, Questionnaire -- To secure additional information from these users, a written questionnaire of 25 questions was developed (see appendix). The questionnaire was mailed to 1,000 of the original letter writers. This is discussed in Part Two of this chapter.

These 1,000 individuals were randomly selected from the 4,000 based on three criteria. First, each user must have purchased his/her aid within five years. Second, writers were grouped according to their brands of aids (See Part II for details). And, third, to insure a level playing field for all brands, questionnaires were sent to an equal number of persons who originally wrote positive letters (34 percent), negative letters (33 percent), or both/neutral letters (33 percent). The number of positive, negative, both/neutral letters per manufacturer followed the same proportions.

Consumer response from both the letters and the questionnaire are grouped around three issues:

Facts About Letter Writers -- Who are the users? How old are they? Where do they live? What is their educational background? What is family income? Do they use one aid or two? How many hours of the day do they wear their aid(s)?

Sales Information -- What brands of hearing aids were purchased by letter writers? From whom did they buy their aids? How much did they pay? Did they receive a trial period? Was there a warranty?

Satisfaction/Disatisfaction -- Did letter writers make positive or negative comments about their aids? Did they make positive or negative comments about the sales agency? Would they return to the same place of business?

Part One Analysis of Letters from Users

1) Facts About Letter Writers

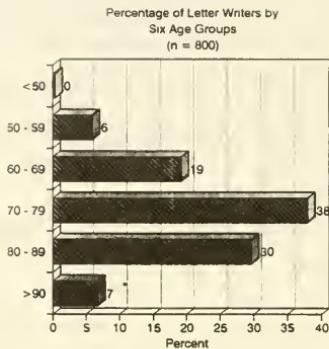
Summary -- Letter writers appear to be older. They come from all parts of the country. More than 80 percent of them have purchased an aid within the last five years, and 66 percent wear their aid(s) all day long. Letter writers were almost evenly split between those who wear one aid and those with two.

Almost 70 percent of the letter writers who stated their ages, were between 70 and 89 years of age. The average age of the respondents who gave their age was 76.5 years.

¹ In total, 8,000 letters were received. Resources did not permit the tabulation of all responses. The 4,000 letters tabulated were selected by the order in which they were received. One hundred twelve letters, which were orchestrated responses, were discarded in reaching the 4,000 total.

ITD assigned one researcher to analyze and code all 4,000 letters.

Figure 2



More than 1,600 letter writers indicated how long they have used hearing aids. One fifth of the respondents have worn hearing aids for more than 20 years. Over 90 percent (92 percent) have worn aids for two years or more.

Letters came from all states and were distributed proportionally almost identically to the percentage of hearing aid sales reported by the industry.

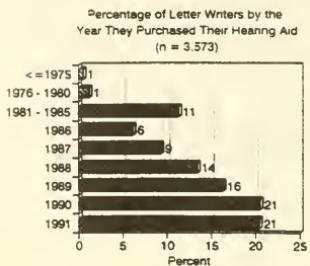
Table 1

Percentage of Hearing Aid Sales to
Percentage of Letters Received
for Five States with Most Sales

State	Sales (HIA) ²	Letters (AARP)
California	10.2	11.7
Florida	7.1	8.4
New York	5.4	6.0
Texas	5.2	6.0
Pennsylvania	4.7	4.9

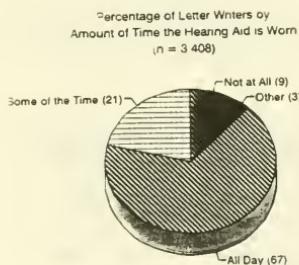
The overwhelming majority of writers (80 percent) purchased their aid within the past five years. More than 40 percent of the respondents purchased their aid in the past two years.

Figure 3



Over half of the letter writers (54 percent) say they own one aid. Just under half (46 percent) own two aids.

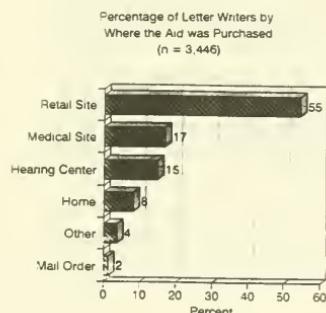
² (Kirkwood, 1991).

Figure 4

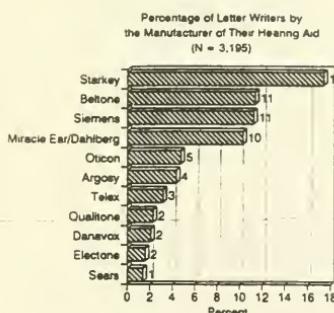
These users regularly wear their aids. Two-thirds of the respondents indicate they wear their aid(s) all day long. Just over 20 percent report they wear their aid some of the time and only 9 percent indicate they don't wear their aid at all.

2) Sales Information

Summary -- The most common sales operation used by letter writers was a retail site, usually staffed by a hearing aid specialist office. Based on information from letter writers, most manufacturers have a relatively small market share. A little more than half (53 percent) of this sample paid \$600 or less and around 5 percent more than \$1,000. The average amount was \$607.

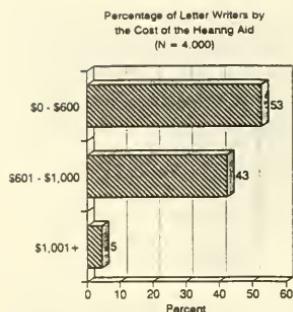
Figure 5

Letter writers purchased their aids from a variety of facilities. Over half (55 percent) bought their aid in a retail site normally staffed by a hearing aid specialist. About 17 percent purchased their aid in a medical site and 15 percent in a hearing center. In-home sales were a little more than 8 percent and mail order sales, less than 2 percent.

Figure 6

About 17 percent of the respondents own a Starkey aid. Next comes Beltone and Siemens with 11 percent each, and Miracle-Ear with 10 percent (Note: Dahlberg manufactures Miracle-Ear). The remaining companies sold to less than 5 percent of the respondents.

Figure 7



A little more than half (53 percent) reported paying less than \$600 for an aid. Of the remainder, 43 percent paid between \$600 and \$999, and 5 percent paid \$1,000 or more for an aid. These figures are consistent with prices recently cited by Consumer Reports.

Table 2

Percentage of Letter Writers by Manufacturer and Price

Manufacturer ³	Percentage \$600 or less	Percentage \$601 to \$1000	Percentage \$1001 or more
Argosy (N = 174)	61	38	1
Beltone (N = 456)	27	67	6
Miracle-Ear/ Dahlberg ⁴ (N = 409)	21	62	17
Oticon (N = 191)	69	30	1
Siemens (N = 452)	68	31	1
Starkey (N = 597)	54	44	2
Telex (N = 129)	64	34	2
Other/Unknown (N = 1,492)	59	36	5

³ Note: A similar analysis was completed based on the questionnaire responses (1000 questionnaires mailed and 858 responses) discussed in Part Two.

Manufacturer	Less than \$600	\$601 to \$1000	\$1001 or more
Argosy (N = 55)	53%	47%	0%
Beltone (N = 80)	24%	70%	6%
Danavox (N = 41)	55%	45%	0%
Electone (N = 36)	66%	34%	0%
Miracle-Ear (N = 92)	11%	61%	28%
Oticon (N = 54)	53%	41%	6%
Qualitone (N = 59)	68%	32%	0%
Siemens (N = 84)	68%	32%	0%
Starkey (N = 97)	57%	39%	4%
Telex (N = 56)	67%	33%	0%

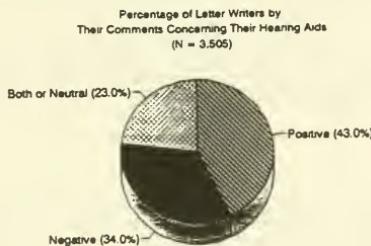
⁴ Based on these letters, Miracle-Ear appears to sell more canal aids than any other manufacturer. Canal aids, as the company points out, are more expensive than in-the-ear or behind-the-ear products. Other companies, however, do have a similar mix of products.

3) Positive/Negative Letters

Summary -- The percentage of letter writers making only positive comments about their aid was 43 percent. Negative letters were 34 percent. The percentage of positive letters was higher for some brands. The most persistent problem articulated by writers was background noise.

Almost all writers ($N = 3,505$) discussed their experiences with their aid. If the writer's comments about his/her aid were all positive, the letter was classified as such. Similarly, only all negative comments led to a negative classification. Letters with both positive and negative or neutral were classified as both/neutral.⁵

Figure 8



Samples

Below are sample letters from users.

Positive Only

"I had anticipated for some years the need for a hearing aid -- I was seventy-seven when I got it...My loss begins just about in mid-voice range and increases with higher frequencies. Since it is in this range that voices and instruments get their quality and timbre, my hearing is quite important to me."

Letter Writer,
Concord, MA

"It's such a joy to go for my walk in the early morning and hear the birds singing, which I could not hear before. It is also a pleasure to hear all of a sermon at church or someone's conversation rather than parts."

Letter Writer,
Ravenswood, WV

Negative

"A year ago...I was told I had an 80 percent loss in my right ear and a 50 percent loss in my left ear. It was decided I need two hearing aids...The left ear aid...was much too powerful, within the next two months they decreased the power but were not able to decrease the background noise...The right ear aid has been back to the plant four times."

Letter Writer,
E. Falmouth, MA

"On August 14, 1990, I bought _____ for both ears. I was not pleased...I feel that I have wasted \$2,348. This has been a sad experience with my hearing aids."

Letter Writer,
Lancaster, CA

Neutral/Both

For your survey, the latest hearing aid that I have is _____. I paid \$550 for it. I put my aid in first thing in the morning...I have a high frequency loss in both ears and though they recommended that I wear two aids, I find it more comfortable with one."

Letter Writer,
Marina Del Rey, CA

⁵ Comments from a number of reviewers were critical of this analysis because the results are not generalizable to all hearing aid users. Instead, reviewers pointed to an industry-funded series of studies called MarketTrack I, II and III (previously referenced). These were conducted in 1989, 1990, and 1991. Consumer satisfaction, as reported in these studies has remained essentially constant varying between 55 and 58 percent in the three studies.

Consumer Affairs at AARP conducted similar letter studies in 1991 and 1992 with different products of significance to older adults. The results of this analysis together with the hearing aid letters are below.

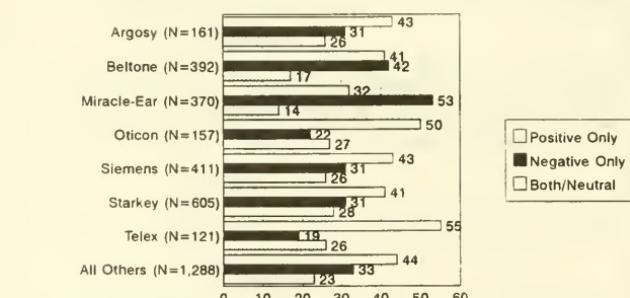
Table 3
Percentages of Letter Writers by Product and Comments

Product	Positive Only Percent	Negative Only Percent	Neutral/Both Percent
Personal Emergency Response Systems (N = 1,848)	34	4	62
Canes (N = 808)	68	4	28
Hearing Aids (N = 3505)	43	34	23
Manufactured Housing (N = 1,134)	17	6	77

The responses varied considerably from product to product. It appears that assistive devices (hearing aids and canes) elicit stronger emotional reactions from readers. There are larger percentages of positive and negative letters with these products, and far fewer neutral/both comments.

An analysis of positive and negative letters according to the brands was also conducted. It found that the percentage of positive letters varied from 32 percent to 55 percent by brand. Negative letters ranged from 19 percent to 55 percent.

Figure 9^a
Percentage of Letter Writers by Nature of Comments and Manufacturer



^a A similar analysis was completed based on the questionnaire responses (1000 questionnaires mailed and 858 responses) discussed in Part Two.

Manufacturer	Percent Satisfied	Percent Dissatisfied	Neutral
Aerofon (N=55)	58	18	24
Bethone (N=80)	39	38	24
Daavon (N=41)	56	20	24
Electone (N=36)	47	31	22
Miracle-Ear (N=97)	41	39	20
Oticon (N=54)	56	22	22
Qualitone (N=59)	41	24	36
Semitone (N=84)	58	19	23
Starkey (N=97)	58	26	17
Telco (N=56)	57	14	32

Almost 1,900 letter writers cited specific problems with their aids. Just over 900, or about a fourth of all writers, mentioned background noise as a specific complaint. After background noise, feedback was the next most frequently voiced complaint with 245 letters or about 6 percent of all writers.

Table 4

Number of Letter Writers Mentioning Problems with their Aid

Problem	Number Complaints	Percentage All (4,000) Writers
Background Noise	912	23
Feedback	245	6
Uncomfortable	198	5
Need Adjusting	196	5
Telephone Trouble	111	3

Part Two

Questionnaire to 1,000 Letter Writers

A follow-up questionnaire of 25 questions was mailed to 1,000 of the original letter writers. These 1,000 individuals were carefully selected from groups using the following criteria:

- Letter writers purchasing an aid within last five years
- Respondents with different brands of aids. Each brand name grouping had at least a 1.5 percent share of the 4,000 respondents
- Similarly, there were two composite groups of letter writers whose brands constituted less than a 1.5 percent share and a composite group of unknown manufacturers, and,
- An equal mix of positive, negative, or both/neutral letter writers overall and with each manufacturers' grouping. That is, 340 positive letter writers received a questionnaire, 330 negative, and 330 both/neutral.

The final selection of respondents was random, based on the above criteria.

Table 5

Number of Questionnaires sent to Respondents by Manufacturer

Brand of Aid	Number Sent	Number Received	Brand of Aid	Number Sent	Number Received
Argosy	80	55	Siemens	100	84
Beltone	100	80	Starkey	100	97
Danavox	60	41	Telex	80	56
Electone	60	36	Group I ⁷	80	47
Miracle-Ear	100	92	Group II ⁸	80	57
Oticon	80	54	Unknown	100	100
Qualitone	80	59			

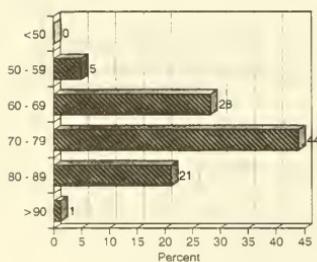
A total of 858 questionnaires (86 percent) were completed and returned to AARP.

1) Facts About Users

Summary -- In general, the respondents to this questionnaire were older, more likely to be white, and more educated than the aging population as a whole. Their household incomes, however, were average.

Figure 10

Percentage of Respondents by Six Age Groups



The average age was 73 years with most respondents between the ages of 66 and 80 years of age. This is similar but slightly younger than the 800 who reported their age from the original letter writers (see figure 2).

Table 6

Percentage of Questionnaire Respondents According to Income

Less than \$8,000	7
\$8,000 to \$11,999	13
\$12,000 to \$20,000	26
\$20,000 to \$27,999	18
\$28,000 to \$35,999	14
More than \$36,000	23

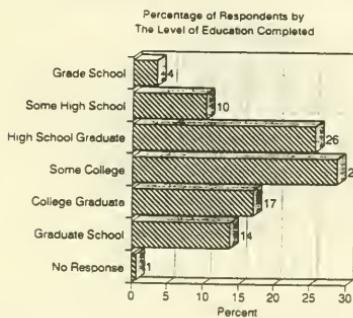
Of those who listed household income, 7 percent reported income of less than \$8,000 per year, 39 percent between \$8,000 and \$20,000 per year, and 23 percent said their household income exceeded \$36,000.

⁷ Group I included the following brands: Audiotone, Bernafon, Dahlberg, Hearing Technology, Maico, NuEar, Omni, Rexton, Sears, and Unitron.

⁸ Group II included the following brands: A&M Limited, Audiovox, Boesch, Ensoniq, Hearing Sciences International, Lang, Lloyd, Magnatone, Marcon, Micro Technologies, Otosonic, Phonic Ear, Phillips, Puretone Limited, Resound, Unimax, Vanco Industries, Viennatone, and Zenith.

More than 80 percent of the respondents completed high school. Almost 30 percent had some college and over 30 percent were college graduates with 14 percent completing graduate school.

Figure 11



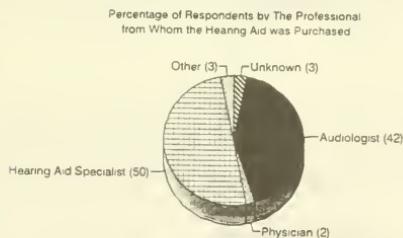
In 1991, only about 12 percent of the 65+ population had completed college, according to census records.

2) Sales Information

Summary -- Hearing specialists sold most questionnaire respondents their aid(s). It also appears that the kind of hearing practitioner selling different brands varies. As with most purchases, a "word of mouth" recommendation was the primary reason why a particular seller was selected. Finally, almost all respondents received a warranty with their aid and most received a 30-day trial period.

Just over half of the questionnaire respondents reported that they purchased their aid(s) from a hearing specialist. About 42 percent purchased their aid from an audiologist and 2 percent from a physician. The remainder indicated someone else or didn't know.

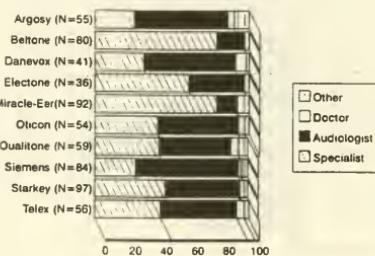
Figure 12



The type of hearing professional selling to respondents varied from manufacturer to manufacturer. For example, 80 percent of the respondents with Beltone or Miracle-Ear products purchased their aid(s) from a hearing aid specialist. Conversely, 65 percent of those with a Siemens product, 60 percent with Argosy, and 58 percent with Danavox purchased their aid from an audiologist.

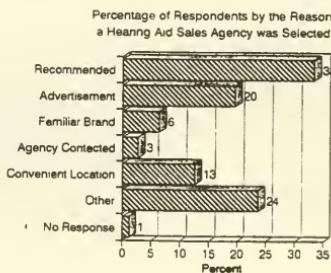
Figure 13

Percentage of Sales by Occupation and Manufacturer



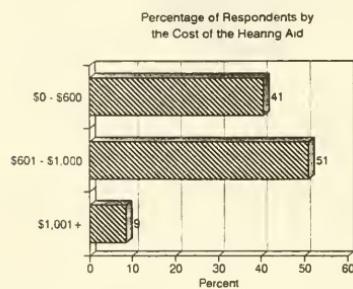
When asked why they visited a particular seller or agency, 33 percent indicated someone recommended it to them. Almost 20 percent indicated advertising was the reason they selected their sales agency and 12 percent indicated location was the reason. Over 20 percent answered "other" as the reason they selected the seller they did.

Figure 14



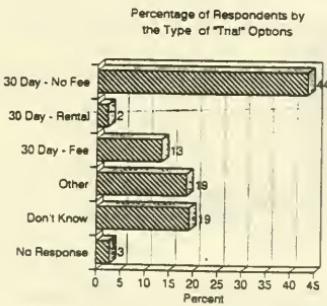
Hearing aid prices for one aid ranged from less than \$150 to more than \$1,800, according to respondents. The average price was \$660. These figures are somewhat higher than letter writers reported and may be explained, at least in part, by the fact that the question asked in the mail-out questionnaire was more complete.

Figure 15



Almost all respondents (85 percent) reported that they had received a warranty for their aid. Over half (58 percent) received a 30 day trial period. Most of these reported no fee for the trial period.⁹

Figure 16

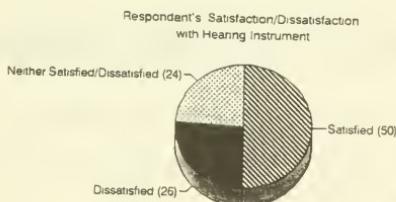


3) Respondents' Satisfaction/Dissatisfaction

Summary -- This questionnaire asked if respondents were satisfied or dissatisfied with their hearing instrument and with the person who tested and fitted them. Half of the respondents reported they were satisfied with their instrument. However, 82 percent reported they were satisfied with the person who tested and fitted them.

When asked if they were satisfied or dissatisfied with their aid, 50 percent of the respondents answered satisfied, 26 percent dissatisfied, and 24 percent neither.

Figure 17¹⁰



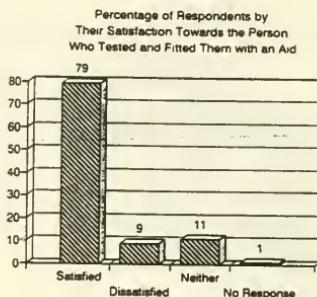
While a positive or negative letter (see figure 8 on page 30) is not the same as "satisfied" or "dissatisfied," they are related. Questionnaire respondents report a higher level of satisfaction and lower level of dissatisfaction with their aid than did the original letter writers. The differences should be considered in light of the fact that questionnaire respondents were originally selected from an equal mixture of positive, negative, and both/neutral letter writers.

⁹ We did not ask about their experience in returning an aid and how much they were charged if they returned the aid.

¹⁰ Figure 17 is added more for clarification than new information. Survey respondents were selected, in part, based on an equal mix of positive, negative, or both/neutral letters. Therefore, it is not surprising that the satisfied percentage should be higher than the number of positive letters reported.

The questionnaire also asked if users were satisfied with the person who tested and fitted them. Almost 80 percent of the respondents were satisfied with the person who tested and fitted them with the hearing aid.

Figure 18



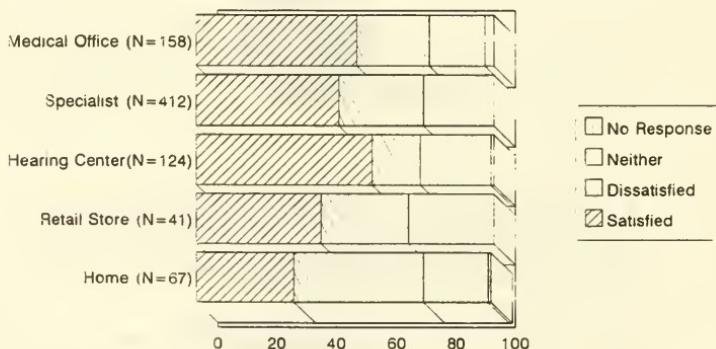
"----- hearing aids are not any better than previous aids...[however,] I do want to stress, that their personnel are fantastic, very easy to talk to and very caring.

Letter to AARP

Satisfaction, according to respondents, varies with the place where the aid was purchased. For example, satisfaction was highest at a hearing center (59 percent). The respondents' satisfaction level was lowest with home sales.

Figure 19

Percentage of Respondents by Satisfaction
With Individual and Place where Aid was Purchased



Conclusion

"They tell you what's in there (the hearing aid), but you don't know what's in there. The difference in prices of hearing aids is absurd. You have no idea what to buy. I told him I can buy a car for that."

Letter Writer

Two items particularly stand out from letter writers:

- While 43 percent of the letter writers spoke positively about their hearing aids, 34 percent were negative, and
- There is considerable variation in the letters in regard to prices, products, and sales facilities.

As the letter writer above points out, many of these items are also related.

The classic definition of consumer satisfaction is a comparison of what one expected versus what one actually received. Did the aid match the advertising or seller's claims, for example? Did the user perceive he/she paid too much for the instrument?

Research indicates that consumers experience problems with about 20 percent of their purchases overall (Andreasen, 1988). Some purchase categories are much higher than others.

But consumer satisfaction/dissatisfaction and complaining behavior is more than repeat business. It's also a catalyst for implementing or scuttling consumer protections (Hunt, 1991).

In 1985, for example, the FTC concluded its Hearing Aid Rulemaking proceeding without enacting a Trade Rule. The Commission decided no Rule was needed (see Chapter One for details). User satisfaction with hearing aids, according to a Commission study, was very high (84 percent). Therefore, no Trade Rule was needed.

Was 84 percent satisfaction realistic? Certainly not today, if ever. Current industry studies indicate overall satisfaction is around 58 percent (Kochkin, 1993). But, according to at least one article, that "rating of only 58 percent" is one of the "key barriers" to growth in hearing aid sales¹¹ (*Audiology Today*, 1993).

As reported in this chapter, although only 4,000 were analyzed, more than 8,000 AARP members who wear hearing aids, chose to share their experiences with the Association. As previously reported, their responses are not generalizable to all hearing aid users. Nonetheless, their positive and negative experiences, as long-time and full-time users provide a unique perspective. These letters indicate that there are consumer problems and complaints to be addressed.

A number of reviewers criticized this report as unscientific and statistically invalid. What they did not point out however, is that consumer complaints are the basis for decision-making and can be a trigger for consumer protection activities.

Probably the most commonly offered consumer tip anywhere is, "check with a Better Business Bureau (BBB) or attorney general to see if there are any complaints." One president of a hearing aid company, in comments to AARP on this report also mentioned this. He advised consumers to contact the BBB or attorney general to "check-out prospective hearing device sellers." However, complaints on file with these agencies are neither random nor generalizable to the entire population. Complainants are self-selected and their complaints are anecdotal. That does not, however, diminish their relevance to buyers, sellers, and consumer protection officials and that is what this report is about.

¹¹ A newly formed industry professional group, the Collaborative Marketing Campaign or CGC, seeks to increase consumer satisfaction to 75 percent by 1995 and 85 percent by the year 2000 (*Hearing Journal*, 1993).

The researcher conducting the MarketTrack studies reported, "clearly this industry has the technology and the skill to achieve 80-90 percent satisfaction."

To be sure, some negative letters relate to personal adjustments the consumer must make. But there are many other issues. Background noise, for example, remains a problem with amplified sound. However, the reasons for it in any given case may be tied to several factors. It could be false expectations raised by advertising or sales personnel. It could be a faulty or improperly recommended aid. It could be an improper fitting or there simply may not be a solution.

User satisfaction should not be considered a simple issue. A hearing aid is not a one-dimensional purchase. There are many players and actions involved with product satisfaction/dissatisfaction. The head of the Department of Veterans Affairs' hearing aid procurement program wrote, "a high quality hearing aid is only good if it is appropriately fitted."

Finally, satisfaction is also related to the fact that users may not want to wear their aid at all. For them it may be at best a necessary evil. To them it symbolizes advanced age and weakness.¹²

It appears that disgruntled letter writers lay their dissatisfaction at the feet of the manufacturers. Satisfaction with hearing evaluators approaches 80 percent. However, as we will see in Chapter Three, consumers should question this. Many hearing evaluators in the two cities studied didn't follow minimum standards when recommending an aid.

The data reported here raises more questions than it answers. However, it is clear that there are problems and complaints. This message should hit home with regulators on both the federal and state levels. Consumers pay when the protections they are promised have eroded and manufacturers and sellers miss an opportunity for increasing market share. The era of "benign neglect" in enforcement has helped neither the consumer nor an industry whose market share is "stagnant."

Comments

Michael Hoke, Argosy Electronics, Inc.

"This report is not a scientific statistically valid report at all... Those individuals who responded felt strongly enough about the questions asked to reply... The opinions they have are very interesting but this in no way accurately characterizes a typical hearing aid experience."

Lawrence Posen, President of Beltone Electronics, Inc.

Stated that as part of the MarketTrack survey of 1991, his firm was provided on a confidential basis, the results for each of the major brands. He volunteered the results for Beltone.

Of 323 Beltone owners surveyed, overall satisfaction was 52 percent and dissatisfaction was 21 percent according to this study.

John Zel, President, Siemens Hearing Instruments, Inc.

"We believe it is extremely important to distinguish between satisfaction and benefit... We believe benefit levels, as opposed to satisfaction levels are relatively high. In other words, most hearing aid purchasers obtain considerable benefit from their hearing aids."

Determining the total cost of a hearing aid is often difficult. Many dispensers,... 'unbundle' their prices setting out separate charges for testing, hearing aid evaluation and the hearing aid itself. As a result, prices across brand comparisons may be somewhat misleading."

Robert M. Krughoff, President, Center for the Study of Services

"Differences in dissatisfaction levels among manufacturers might result from differences in the kinds of customers they have attracted. Possibly the marketing strategy, price levels, hearing aid types, or other features..."

Peter Hahn, President, Oticon, Inc.

"It would be expected that consumers would have more confidence in the provider... First, manufacturers are often blamed... Second, the manufacturer is distant... So the confidence could naturally be centered on the more personal relationship with the provider."

¹² Note however, AARP received a higher percentage of positive letters about canes than hearing aids. A cane is in many ways a more visible symbol than a hearing aid. A hearing aid, of course, is a much more complex device and purchase.

Chapter Three

Shopping Experience Study

"As a layman...you're going to have to take them at their word....This \$400 aid is no good for you, an \$800 or \$1200 aid is what you need. The criteria is you [the consumer] don't know. You're going to have to take them at their word."

Consumer Tester
Retired Policeman

Sixteen teams of consumer testers shopped for hearing aids at 23 different sales agencies in Tampa, and West Palm Beach, FL during the summer and fall of 1992. All told, consumer testers made 169 visits to 23 different sites. At each site, one member of each team had his/her hearing evaluated. Their findings included the following:

- There were a total of 169 evaluations which lasted from 10 minutes to 105 minutes.
- 57 percent of the consumer testers received recommendations to buy a hearing aid. In Tampa, one seller recommended that only 33 percent of the consumer testers needed an aid, while a different seller recommended that 80 percent of the same consumer testers needed an aid.
- Half of the sellers failed to follow state testing regulations when recommending an aid.
- 26 consumer testers in 11 sites complained of noisy test rooms.

Introduction

This consumer hearing aid inquiry consists of two parts. Chapter Two looked at the experiences of 4,000 users. This chapter looks at consumer tester experience in shopping for an aid. Most consumers are inexperienced shoppers when it comes to medical devices. We rely upon health professionals to provide reliable evaluations of our condition. Reliable evaluations should lead to accurate fittings and after the device is sold, we expect continuing quality service.

When we place our trust in the hands of practitioners, we want to know they're competent and follow good standards of practice. As we saw in Chapter One, both federal and state governments regulate the market, but the principal responsibility for consumer sales rests in the hands of state licensing boards.

The question is, how effective is this regulatory scheme at ensuring reliable hearing evaluations and proper fittings? At least one recent study raises serious questions about hearing aid specialist boards (Lewis and Powers, 1992).

AARP's Consumer Affairs Section set out to document facts about the marketplace for hearing aids in a case study format.

The Association commissioned this study to answer the following questions:

1. What procedures are followed and what representations are made at different sales agencies?
2. What is the level of compliance with state and federal regulations? And,

3. What, if any, unfair, unethical, or apparently illegal activities are practiced?

For this study, older consumer testers were used to report on their experiences shopping for an aid. At each facility one team member received a hearing evaluation and in 57 percent of the visits, sellers recommended an aid. After each evaluation, both team members (the observer and the tester) recorded what happened on special reporting forms. Their reports are the basis for the findings described below.

In terms of their hearing ability, the consumer testers were a mixed group. Some regularly wore aids, some had a hearing loss but didn't wear an aid, and others had no hearing loss and no need for an aid. The ITD audiologist would have recommended that 45 percent of the consumer testers evaluated needed an aid.

Consumer testers were used because this is the only way to document some market practices. It is a widely accepted methodology that the courts recognize. In a 1979 decision, the U.S. Supreme Court held that even if consumer testers didn't plan to buy, they had standing to file claims under the federal Fair Housing Act. This was for violations found while shopping for a home (*Gladstone Realtors v. Village of Bellwood*).

The results of this research are anecdotal in nature and aren't necessarily representative of other locations. However, this study together with other research, raises questions about the efficacy of the regulatory scheme in place and the marketplace itself.

Methodology

In Tampa, 12 consumer testers were recruited and in West Palm Beach, 20. Consumer testers visited each sales agency in teams of two. First, however, they received a detailed training in the various elements of a hearing evaluation, the nature of hearing aids, and what to look for. One member of each team also received a hearing evaluation from a certified Ph.D. audiologist from the Institute for Technology Development (ITD).

Volunteer testers were recruited at senior centers, consumer protection offices, volunteer organizations, and by personal referrals. To protect their privacy, consumer testers gave fictitious names and addresses to sellers. However, they were instructed to be truthful in all other ways and specifically not to feign a hearing loss. While a few consumer testers were actually shopping for an aid, most had no intention of buying. They volunteered to be "guinea pigs" for this research. All expenses were reimbursed and each consumer tester received a small honorarium.

Sites -- Because of costs and the need for close monitoring, this study was limited to two sites in one state. Florida was chosen because of its growing aging population, large hearing aid sales (second only to California), and strong regulatory standards.

Florida's regulations for hearing evaluations are among the strongest in the country. They are equal to or stronger than a number of other states¹ with a large population of older adults. Florida's regulations also reflect accepted standards of practice.²

Florida receives about 200 hearing aid complaints a year and takes about 36 disciplinary actions per year against hearing aid specialists. It ranks among the top states in terms of disciplinary actions against licensees (Lewis and Powers, 1992). Florida's licensing boards have a full range of powers to take against bad actors. The board is not proactive, however, in investigating compliance with its standards.

¹ For example, in five populous states with a large aging population: California and New York have no minimum standards of practice. Illinois, Pennsylvania and Texas have standards similar to Florida's. While Florida licenses both audiologists and hearing specialists, the standards of practice are identical.

² For example, the American Speech-Language-Hearing Association's (ASHA) Preferred Practice Patterns includes the same tests required by Florida regulations. ASHA's standards include other tests not specified in Florida's regulations.

Florida currently licenses 1,750 hearing aid practitioners, 600 audiologists and 1,150 specialists. Of these practitioners, only 528 audiologists and 730 specialists are active licensees.

After a preliminary review, ITD selected Tampa and West Palm Beach as the two test sites. Both are medium-sized cities where volunteer testers could conveniently visit each seller listed in the phone book.

Table 7

Summary Hearing Aid Sales Agencies Visited in Tampa

Site	Type	Personnel
1	Hearing aid retail ³	Hearing aid specialist
2	Hearing center	Audiologist, CCC-A
3	Hearing aid retail	Hearing aid specialist
4	Hearing center	Audiologist, CCC-A
5	Hearing aid retail	Hearing aid specialist
6	Hearing aid retail	Audiologist, CCC-A
7	Hearing aid retail	Hearing aid specialist
8	Hearing aid retail	Hearing aid specialist
9	Hearing aid retail	Hearing aid Specialist
10	Physician office	Audiologist, CCC-A
11	Hearing center	Audiologist, CCC-A
12	Hearing aid retail	Hearing aid specialist

In Tampa, there were 12 distinct sellers within city limits listed in the Yellow Pages. Six teams of consumer testers visited each seller. That is, one member of each team scheduled a hearing evaluation at each sales agency. Both team members reported what happened. Where two sales operations were operated by the same owner, one of the two was selected by the toss of a coin.

Table 8

Summary Hearing Aid Sales Agencies Visited in
West Palm Beach

Site	Type	Personnel
13	Hearing aid retail	Hearing aid specialist
14 ⁴	-----	-----
15	Hearing aid retail	Hearing aid specialist
16	Hearing center	Audiologist, CCC-A
17	Hearing aid retail	Hearing aid specialist
18	Hearing aid retail	Hearing aid specialist
19	Hearing aid retail	Hearing aid specialist
20	Hearing aid retail	Hearing aid specialist
21	Hearing aid retail	Hearing aid specialist
22	Hearing center	Audiologist, CCC-A
23	Hearing Aid Retail	Hearing aid specialist
24	Hearing aid retail	Hearing aid specialist

³ Hearing aid retail indicates hearing aid sales only. Hearing center indicates comprehensive hearing services.

⁴ In almost every instance, the hearing aid specialist at this facility required each tester to visit a physician before conducting an evaluation. Therefore, this facility is not included in percentages or totals.

In West Palm Beach, the phone book listed 12 distinct sellers with a street address within city limits. Ten teams of consumer testers visited each seller. One sales agency had personnel that served offices in two communities. Consumer testers scheduled their appointments at the most convenient location.

The 23 facilities in these two cities included all three types of hearing aid sales agencies. Consumer testers visited 17 retail sites, five hearing centers, and one physician's office which sells hearing aids. Sellers included 16 hearing aid specialists and seven audiologists.

There were only a few sites where teams were unable to make appointments.

**Florida Department of Professional Regulation,
Board of Hearing Aid Specialists**

***484.0501 Minimal procedures and equipment...**

(1) The following minimal procedures shall be used in the fitting and selling of hearing aids:

- (a) Pure tone audiometric testing by air and bone to determine the type and degree of hearing deficiency...
- (c) Appropriate testing to determine speech reception thresholds, speech discrimination scores, the most comfortable listening levels, uncomfortable loudness levels, and the selection of the best fitting arrangement for maximum hearing aid benefit...

(4) ...If, upon inspection of the ear canal with an otoscope...and upon interrogation of the client there is any recent history of any infection or any observable anomaly, the client shall be instructed to see a physician, and a hearing aid shall not be fitted...

***21J.6.005 Disclosure Required When a Significant Difference Between Air and Bone Conduction Exists.**

Any person with a 15 dB (decibel) difference between air conduction and bone conduction hearing...must be advised of the possibility of medical correction.*

**Federal Regulations
21 CFR 801.420**

A hearing aid dispenser should advise a prospective hearing aid user to consult promptly with a licensed physician...before dispensing a hearing aid if the...user has any of the following conditions:...

- (vi) Audiometric air-bone gap equal to or greater than 15 decibels at 500 hertz (Hz), 1000 Hz, and 2,000 Hz.
- (vii) Visible evidence of significant cerumen (ear wax) accumulation or a foreign body in the ear canal...

Federal law restricts the sale of hearing aids to those individuals who have obtained a medical evaluation from a licensed physician. Federal law permits a fully informed adult to sign a waiver statement declining the medical evaluation for religious or personal beliefs...The exercise of such a waiver is not in your best health interest and its use is strongly discouraged.*

Findings

Overall, consumer testers reported that their 169 hearing evaluations took from ten to 105 minutes to complete. The average evaluation took 49 minutes. However, almost a third of the consumer testers were finished in less than 30 minutes.

The evaluations provided to consumer testers in many of the 23 facilities exceeded both state and federal standards. However, the principal finding of this research was hearing evaluators appeared to ignore legal requirements for good practice. Half⁵ of the sales agencies visited failed to follow the state's minimum evaluation standards when recommending an aid. What's worse, sellers prescribed hearing aids for 41 percent of the consumer testers without conducting the most basic tests (air and bone, see below).

In addition, hearing professionals appeared to ignore federal regulations requiring consumers to be examined by a physician first and appeared to engage in false and deceptive practices.

Evaluation Standards -- To comply with Florida regulations, each hearing evaluation should include the following items:

- **Otoscopic Examination** (an otoscope is a lighted device used to examine the ear canal).
- **Pure-tone Air Test** (measures the subject's reception of air-conducted sound).
- **Pure-tone Bone Test** (measures the subject's reception of sound vibrated through the bones of the head).
- **Speech Reception Test** (measures the lowest volume level where a subject can distinguish 50 percent of two-syllable words).
- **Speech Discrimination Test** (measures the ability to understand one-syllable words presented at a comfortable sound level).
- **Most Comfortable Loudness Test** (measures the most comfortable sound level for a subject).

Otoscopic Examination -- An otoscope is used to examine each subject's ear. With this device the evaluator can determine if there is any blockage (excessive ear wax, for example) or if there is any evidence of possible disease. If either condition exists, the evaluator should refer the subject to a physician.

Some of the consumer testers used in this shopping investigation, in fact, did have problems. In the preparatory hearing evaluation, the ITD audiologist found two consumer testers with excessive ear wax and two with symptoms of disease (inflamed or red ear canals and discolored ear wax).⁶

These conditions went unnoticed by nine evaluators. This occurred because sellers never examined the ears of these prospective customers with an otoscope.

Audiometric Examinations -- For the remaining tests an audiometer is used. This is an electronic device producing sounds at various frequencies and intensity. It's also used to play back lists of certain pre-recorded words at various volume levels for patient recognition. Subjects listen through ear phones and signal their recognition of sounds or words.

⁵ None of these testers purchased an aid. Therefore, it is possible some evaluators may have conducted additional tests if a sale had been consummated.

⁶ Two others had symptoms of middle ear problems. This was revealed through case histories and abnormal tests of the middle ear function (tympanograms).

Pure-tone air is comparable to the kind of screening almost every school child receives. Pure-tone bone evaluations are similar. Both are critical to a proper hearing evaluation and are required by both federal and Florida state regulations. These tests are called pure tone audiometry.

Without conducting pure-tone bone tests, an evaluator cannot determine where the hearing loss originates (outer, middle, or inner ear). Problems with the outer and middle ear are generally medically treatable. Without determining where the loss occurs, a treatable problem may remain undetected. Further, recommending a hearing aid for a patient with a treatable condition could actually damage their hearing.

The recognition of an organic cause for hearing impairment is of extreme importance to the health and safety of the hearing-impaired patient.

FDA Commissioner
(42 Fed Reg 31, [1977])

All of the consumer testers for whom an aid was recommended did receive a pure-tone air test, but only 62 percent of the consumer testers received pure-tone bone testing. In Tampa, sellers at one site never conducted pure-tone bone tests on any consumer tester. They did, however, recommend aids to 90 percent of the consumer testers. In West Palm Beach one site never conducted these tests. In other sites in both cities, practitioners conducted pure-tone bone tests erratically.

Speech reception, speech discrimination and most comfortable loudness, called speech audiometry, are less important than pure tone audiometry to the patient's health. But they are important to fitting the appropriate aid.

Table 9
Percentage Hearing Tests Provided by Site
As Reported by Tampa Consumer Testers

Site	Otoscopic Exam	Air Test	Bone Test	Speech Reception	Speech Discrimination	Most Comfortable Loudness
1	100	100	66	50	50	50
2	100	100	100	83	83	83
3	100	100	83	0	0	0
4	66	100	100	100	83	66
5	100	100	0	0	0	0
6	83	83	17	17	33	17
7	100	100	60	60	60	40
8	100	100	80	60	60	60
9	100	66	0	66	66	20
10	100	100	100	100	100	83
11	100	100	83	100	100	83
12	100	100	80	80	40	80

Table 10
 Percentage Hearing Tests Provided by Site
 As Reported by West Palm Beach Consumer Testers

Site	Otoscopic Exam	Air Test	Bone Test	Speech Reception	Speech Discrimination	Most Comfortable Loudness
13	100	100	67	55	78	67
14	-----	---	---	-----	-----	-----
15	100	80	80	60	60	60
16	100	100	75	63	50	63
17	100	100	70	70	70	60
18	100	90	70	80	80	70
19	100	100	20	40	50	50
20	100	70	60	70	70	80
21	100	90	50	30	40	50
22	100	100	100	100	100	100
23	20	80	0	10	30	40
24	100	100	30	30	40	50

Table 11
 Compliance with Minimum Standards
 Tampa

Site	Percentage Consumer Testers Recommended an Aid	Of Those Recommended an Aid, Percentage Receiving Minimum Tests
1	66	50
2	50	100
3	33	0
4	33	100
5	0	NA
6	50	0
7	40	50
8	80	75
9	33	0
10	33	50
11	50	100
12	80	50

"Improvements in the quality of hearing aid health care services depend largely on hearing aid dispensers recognizing their obligation to achieve greater competency in testing hearing in order properly to select and fit a hearing aid."

FDA Commissioner
 (42 Fed Reg 31, [1977])

Table 12

Compliance with Minimum Standards
West Palm Beach

Site	Percentage Consumer Testers Recommended an Aid	Of those Recommended an Aid, Percentage Receiving Minimum Tests
13	67	33
14	-----	-----
15	60	83
16	50	40
17	70	67
18	30	100
19	60	33
20	30	30
21	70	50
22	70	67
23	90	0
24	80	25

In Tampa, apart from one site that recommended no aids, the percentage of consumer testers recommended an aid ranged from 33 percent to 80 percent. In West Palm Beach, the range was from 50 percent to 90 percent.

Facilities -- Florida regulations and good practice demand that background noise (sound pressure) not exceed certain levels in any facility used for audiometric testing. That is, background noise must be limited. Excessive noise can skew audiometric tests thereby leading to the wrong fitting.

In 11 sites, 26 consumer testers reported their evaluation was conducted in what they described as a "noisy room." To be sure "noisy" is a subjective term, but if a consumer tester is distracted by extraneous noise during an evaluation, something is wrong.

Consumer testers reported that they heard: traffic noise, the hum of an air conditioner, people talking in the next room, a gardener working outside, or people walking in and out of the room. Whether the room was noisy or quiet could vary by the time of day (rush hour traffic, for example) or whether or not the professional chose to use his/her hearing booth. In four instances, evaluators performed audiometric tests in the same room as, but outside a hearing booth. Consumer testers who asked were told a sound booth was unnecessary.

Several volunteers reported the equipment used sometimes appeared to vary with the professional's perception of whether or not the consumer tester was really interested in buying an aid.

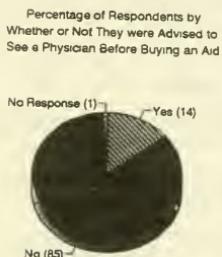
FDA's Requirement for Medical Examination -- FDA regulations restrict hearing aid sales to individuals who have first obtained a medical evaluation. A hearing aid cannot be sold unless the patient presents "a written statement signed by a licensed physician...[stating] the patient's hearing has been evaluated." Fully informed consumers can waive this right, but they must sign a waiver. The seller should also inform "the prospective user that the exercise of the waiver is not in the interest of the user's health."

A medical evaluation is required to determine if the hearing loss is medically treatable. Based on consumer tester reports, it appears that a significant number of hearing professionals ignored this requirement.

None of the consumer testers presented a statement from a doctor but none of them actually purchased an aid. It is possible consumer testers could have been asked to see a doctor before or after a sale was completed. However, according to consumer testers, most sellers were anxious to place an order that day, without incurring any delays to see a doctor or anything else.⁷

Overall, only 19 percent of the consumer testers reported that sellers advised them to see a physician before they purchase an aid. In Tampa the percentage was 17 percent and in West Palm Beach 21 percent.⁸

Figure 20



This is strikingly similar to what questionnaire respondents reported (see Chapter Two for details). A majority of the survey respondents visited their doctor before buying an aid. However, of the 30 percent who did not ($N=257$), only 14 percent were advised that it was in their best interest to see a physician first and only 17 percent signed the waiver required by the FDA.

"He definitely recommended hearing aids, two. They...[cost] \$650 for one or two, \$1,200. But if we didn't [buy] that day, the price would be \$750 for one."

Consumer tester

Unfair and Deceptive Practices -- Apart from the testing and equipment standards, Florida's regulations also prohibit certain acts and practices which are considered unfair and deceptive. These would include:

- False or misleading advertising
- False or misleading representations
- Making predictions or prognostications about the future course of a patient's hearing impairment
- Making statements that a hearing aid will retard the progression of a hearing impairment
- Making any statement regarding the cure of the cause of the hearing impairment by using an aid
- Failing to post a copy of the professional license and,
- Failing to post a sign stating that itemized prices are available

⁷ FDA Commissioner Kessler recently stated on NBC's "Dateline" that, "Waivers are being overused and misrepresented. The system's not working. The system must change."

⁸ Note, site number 14 was not included in the calculation of this percentage.

Violations can lead to disciplinary actions against the seller.

Consumer testers reported a number of instances that appeared to be unfair or deceptive. There were what appeared to be patterns of violations, such as a failure to post the required documents or false pricing. However, most of what appeared to be violations were a series of isolated incidents. They were nonetheless troubling because of the implications raised. The items reported by consumer testers included the following:

- 1) In a number of cases, sellers recommended aids for consumer testers who were clearly not candidates.
- 2) One seller made claims that the consumer tester would be able to hear all the high tones when in crowded areas with a particular aid. This aid would also filter out other noises.
- 3) One stated it was in the consumer tester's best interest not to see a physician before purchasing a hearing aid.
- 4) One stated a trial period was unnecessary since that particular aid used 24K gold circuits to make the sound most natural.
- 5) One stated a hearing aid would "exercise the nerve and slow down the hearing loss." As well, this aid would be good for up to ten years.
- 6) One promised the "hearing loss would slow down with hearing aids." This seller also described himself as a "graduate audiologist" without posting such a license.
- 7) One stated that a hearing aid was needed right away and coupled this with a refusal to provide price information until a sale was completed.
- 8) One stated that an aid is needed because "your right ear canal is collapsing and [the aid] will help control that."⁹
- 9) In one instance there was what appears to be false pricing in an advertisement. The ad stated that the price for an aid was reduced from \$495 to \$249. However, the consumer tester was told the price for this aid was always \$249.
- 10) One seller advertised "free hearing evaluation" but charged for the test when the consumer tester indicated he was not going to buy an aid that day.
- 11) In Tampa, according to consumer testers, only 67 percent of the sites had an occupational license posted. In West Palm Beach, every seller had his/her license posted. And,
- 12) In Tampa, according to consumer testers, 75 percent of the sellers had a sign stating itemized prices were available. In West Palm Beach, only 67 percent of the sellers had such a sign posted.

"I guess I've never given hearing aids much of a thought before. But after this [shopping experience study], it's a scary thought should one of us need one."

Consumer Tester

Comments of Consumer testers

The volunteer testers were asked to summarize their thoughts after completing this study. Generally, consumer testers believed the person who evaluated their hearing acted as if he or she knew what to do. Consumer testers were unsure about exactly how to determine the quality of the evaluation and the value of the hearing aids sold.

⁹ A hearing aid would limit the collapses of an ear canal. However, a \$600 to \$1,000 aid is not needed to correct a collapsed ear canal. There are other remedies that are far less costly.

In both Tampa and West Palm Beach, consumer testers generally agreed they would likely visit a particular site in that city if they needed an aid. They chose this particular site because of what appeared to be the thoroughness of the evaluation and the professionalism of the staff. Consumer testers also commented on the "understanding" of the staff at this site.

In both instances, the sites selected were hearing centers staffed by audiologists.

When asked what recommendations they would give to first-time buyers they answered:

- Buyer Beware!
- Shop around!

Conclusion

Based on letters from AARP members (see Chapter Two), it appears that many long-time users are not satisfied with their hearing aids. On the other hand, they appear to be very satisfied with the persons selling them the product. Is this higher satisfaction level justified, however?

While the results are anecdotal in nature, the shopping experience study outlined in this chapter raises questions about widespread satisfaction with sellers.

To be sure, many of the hearing evaluations consumer testers received at the 23 sales agencies visited were professional and thorough. However, the quality of these exams and the conclusions drawn from them varied extensively.

Overall, evaluators recommended to 57 percent of the consumer testers that they needed a hearing aid. However, the differences between sellers with the same pool of consumer testers was startling. In one Tampa site, 33 percent of the consumer testers received a recommendation that they needed an aid. In another site, 80 percent were recommended an aid. In West Palm Beach, the range went from 50 percent of all sellers to 90 percent. By contrast, the ITD audiologist would have recommended an aid for 45 percent of the consumer testers.

Obviously, practitioners will disagree, but when the range of recommendations between sellers is 40 to 50 percentage points, there are serious questions about current standards of practice.

What's worse, half of the consumer testers who received a recommendation for an aid, never were given one or more of the minimum tests required by Florida's state regulations and 41 percent of those recommended to purchase an aid never received a pure tone bone test, one of the most basic tests in any hearing evaluation.

As a group, audiologists had a higher compliance rating with Florida's minimum standards than did hearing aid specialists.

Many consumer testers complained of being tested in "noisy rooms," contrary to state requirements. Others highlighted what appeared to be unfair and deceptive practices. Finally, only 19 percent of the sellers referred consumer testers to a physician.

Beyond the question of satisfaction, this shopper experience study found that consumer protection regulations are no guarantee that the hearing evaluation a consumer receives is complete or accurate. Florida has one of the better licensing laws in the country with specific standards of practice. Apparently, however, their enforcement activities are limited to complaints.

When it comes to buying a medical device like a hearing aid, however, older consumers usually don't know what appropriate testing standards should be. It's often a question of not even knowing what you don't know.

After reviewing this shopping experience study, it is unfair to say sellers are only pushing a product but it is fair to warn consumers that in many ways, they have been and continue to be on their own in shopping for hearing aids.

Comments	<p><i>Lawrence Posen, president, Beltone Electronics Corporation.</i> <i>"The shopper study...provides very useful consumer information and clearly indicates the need for further standardization of fitting practices... Additionally, it clearly indicates a need for states to take a more proactive stance..."</i></p> <p><i>Your report mentions that sellers recommend aids for testers who were not candidates. Your report should also mention...aids were not recommended for testers who could have possibly benefitted from their use."</i></p> <p><i>E. Renee Alsobrook, chief, Bureau of Investigative and Consumer Services, Florida Department of Business and Professional Regulation.</i> <i>"The draft provides significant justification for proactive regulation...I would look forward to presenting the report to the Florida Legislature..."</i></p>
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Conclusion, Recommendations, and Shopping Tips

Hearing aids are an important consumer issue of special significance to older consumers. Hearing loss affects more than 23 million people, most of whom are over 60 years of age. The cost of an aid on average is more than \$600. It also appears that about half of all users wear two aids. Altogether, hearing aid sales top more than a billion dollars a year.

While the same kinds of chips may be used in manufacturing a hearing aid as in consumer electronics, buying an aid is not like purchasing a color television, VCR, or stereo. The buyer's hearing must be carefully evaluated and the hearing aid fitting should try to match the patient's hearing loss. By the nature of the purchase, the buyer must rely upon the seller for advice and expertise.

The number and complexity of hearing instruments, the various occupations evaluating hearing, the lack of consumer knowledge about hearing aids, particularly for first-time buyers, and the absence of proactive governmental oversight creates a milieu for consumer problems.

This study was designed to ask basic consumer questions about hearing aids. The questions were about price, product, satisfaction, sales, and users. We wanted to capture a snapshot of the marketplace from the perspective of users and buyers. What we learned is that there are problems in the marketplace. This report identifies some of them. Prominent among them are:

- A need for continuing federal regulatory activity. For almost ten years, there have been few regulatory actions taken by federal agencies. For example, background noise is a problem for users and no product on the market can solve the problem. Yet advertising promising to eliminate background noise has been airing on television for years. However, it took the head of the FDA to say: "enough." We applaud the recent attention paid by the FDA, but recommend the agency establish procedures to regularly monitor the market and enforce their regulations on an ongoing basis. The FDA may not have an activist commissioner in the future. Similarly, the FTC must take a more aggressive stand.
- A need for state hearing aid specialist and audiologist licensing boards to be proactive in enforcing standards of practice. Clearly this report is limited in scope to a small shopping experience study in only two cities. However, when recommendations to purchase a hearing aid range from 30

percent to 80 percent with the same pool of testers there is a problem. Similarly, tough regulations are great on the books, but if they're not enforced, they're meaningless. In our study, sellers recommended aids to 41 percent of the testers without conducting the most basic of hearing tests, the pure tone test. Yet many states, including Florida, where this shopping test took place, require such tests before a practitioner can sell an aid. Consumers don't know what it is they don't know about hearing aids. Buying an aid is a new experience to an older and often more trusting consumer. Placing the major burden solely on the shopper clearly invites abuses.

Effective oversight cannot eliminate consumer problems, but it can improve the current condition. Specific recommendations are that:

- States should enact licensing laws with minimum standards of practice (particularly for hearing evaluations), raise competency standards for licensees testing and fitting aids, establish a 30 or 60-day return policy in those states that have not enacted such a law, and a careful listing of unfair and deceptive acts and practices for this market.
- Consumer groups, in communication with industry representatives and organizations that represent practitioners, should develop a model state statute for licensing hearing aid sellers in all states. Such a model could be used in policymaking.
- Federal and state regulators must become proactive in policing the marketplace to insure competency, integrity, fairness, and accuracy. Relying merely on complaint activity from a population that is reluctant to complain and uneducated in the testing for and purchase of these devices is a form of tunnel vision. Regulators should also take an active role in both educating consumers on how to make complaints and in facilitating complaint making through toll-free telephone numbers and other mechanisms.
- The FDA should continue in its course of requiring clinical data to substantiate manufacturers' claims. Hearing technology has changed dramatically since 1977, when the FDA first had jurisdiction over this product. New products should not continue to be grandfathered as "substantially equivalent" to those on the market in the 70s. The FDA should initiate random audits to insure there is compliance with its regulations about being examined by a physician before purchasing a hearing aid.
- Aging organizations should initiate an educational campaign, working with the industry and practitioners, to promote the use of hearing technology. The campaign should consist of information about products and about the hearing evaluation process and best practices for fitting and selling hearing aids.
- Both manufacturers and sellers should develop standards of ethics for advertising hearing aids. An advisory group of users, practitioners and industry representatives could help evaluate hearing aid ads.

When shopping for a hearing aid, AARP recommends consumers become careful shoppers. Shopping tips which should assist buyers include the following:

- 1) Be an educated consumer. Go to the library and learn about hearing aids and hearing evaluations prior to purchasing. There are a number of excellent books written for first-time buyers.¹ Learn about service providers and the range of services and products they offer. Check your telephone's Yellow Pages for practitioners in your area.

¹ Consumers can also write AARP for a free copy of an award winning guide to hearing aids.

Write: Product Report: Hearing Aids (D13766)
AARP (EE0458)
PO Box 22796
Long Beach, CA 90801-5796

(Allow four to six weeks for delivery.)

- 2) If you're a first-time buyer, be sure to visit a physician, preferably a specialist in treating hearing impairments, for a medical examination before buying an aid.
- 3) Try to have your hearing evaluated by a certified audiologist. Audiologists generally are the most knowledgeable of the practitioners that evaluate and fit hearing aids. They also conduct the most thorough evaluations.
- 4) Be on your guard. There are practitioners in all occupations who are more interested in a sale than your welfare.
- 5) Secure a written quotation for the hearing test, hearing aid and all other associated costs. Costs do vary but shouldn't be the only consideration in buying an aid.
- 6) Secure a copy of your audiogram in addition to any other hearing test results. If you don't understand test results, ask more questions.
- 7) Be skeptical about any claims made for the product and any high pressure tactics.
- 8) Demand a 30 to 60-day trial period to test the aid in your hearing environment. The cost to you if you return the aid, should be minimal. Be sure to ask how the trial period works.
- 9) Practice with the aid during your trial period and attend all scheduled follow-up sessions.
- 10) Accept the fact that even the best aid, fitted by the most competent individual may need to be remade or adjusted. It is also the consumer's responsibility to work with the seller.
- 11) If you're not satisfied, return the aid within the trial period.
- 12) If necessary, file a complaint with the state licensing board, your attorney general, and the Federal Trade Commission or the Food and Drug Administration.

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Appendix

AARP Bulletin

September 1991

Write and tell us your experiences

Do you own a hearing aid? If you do, the Association wants to hear from you.

AARP is studying consumers' use of hearing aids and would like to include information about users' experiences in a report. Please write and tell us:

■ the brand name of your aid and the date of purchase;

■ price paid for one or two aids;

■ whether you use your aid all, most, some of the time or never;

■ where you bought your aid--at home, or from a dispenser's office or a medical office; and what has been your experience with the aid?

Send your letter, including your name, address and telephone number, to: Hearing Aids, AARP Consumer Affairs, 601 E St. N.W., Washington, D.C. 20049.

AARP will contact some respondents for further information.

Identification Number

(Place I.D. # Label Here)

INSTRUCTIONS

PLEASE ANSWER THE FOLLOWING QUESTIONS ABOUT YOURSELF. ALL INFORMATION ON THIS SURVEY WILL REMAIN STRICTLY CONFIDENTIAL.

1. What was your age on your most recent birthday? _____

1

2. What is your marital status? (Check one)

- (a) _____ Married
- (b) _____ Single
- (c) _____ Widowed
- (d) _____ Divorced

2

3. Please check the box that includes your annual household income. By household income we mean your income, the income of your spouse and any other income from which you benefit directly. (Check one)

- (a) _____ Less than \$ 8,000
- (b) _____ \$ 8,000 to less than \$12,000
- (c) _____ \$12,000 to less than \$16,000
- (d) _____ \$16,000 to less than \$20,000
- (e) _____ \$20,000 to less than \$24,000
- (f) _____ \$24,000 to less than \$28,000
- (g) _____ \$28,000 to less than \$32,000
- (h) _____ \$32,000 to less than \$36,000
- (i) _____ \$36,000 and above

3

4. Which race do you consider yourself to be? (Check one)

- (a) _____ African American (Black)
- (b) _____ Caucasian (White)
- (c) _____ Asian
- (d) _____ Other _____

4

5. Do you consider yourself to be of Hispanic origin? (Check one)

- (a) _____ Yes
- (b) _____ No

5

6. Which is the highest level of education you have completed?
(Check one)

- (a) _____ Grade school or less
- (b) _____ Some high school
- (c) _____ High school graduate
- (d) _____ Some college
- (e) _____ College graduate
- (f) _____ Graduate or professional degree

6

7. Which style of hearing aid do you have? (Check one)

A. 

Canal Aid

B. 

In-the-Ear Aid

C. 

Behind-the-Ear Aid

D. Other

7

INSTRUCTIONS

WE WOULD LIKE TO LEARN ABOUT YOUR MOST RECENT HEARING AID PURCHASE EXPERIENCE. PLEASE ANSWER THE FOLLOWING QUESTIONS ABOUT THE LAST HEARING AID YOU PURCHASED, EVEN IF YOU ARE NOT USING IT.

8. How much does your hearing problem WITHOUT YOUR HEARING AID stand in the way of your doing the things you want to do? (Check one)

- (a) Does not interfere at all
- (b) Some
- (c) A great deal
- (d) Don't know

8

9. How much does your hearing problem WITH YOUR HEARING AID stand in the way of your doing the things you want to do? (Check one)

- (a) Does not interfere at all
- (b) Some
- (c) A great deal
- (d) Don't know

9

10. Are you satisfied or dissatisfied with your hearing aid? (Check one)

- (a) Satisfied with the hearing aid
- (b) Dissatisfied with the hearing aid
- (c) Neither satisfied nor dissatisfied

22

11. Think about the experience you had being tested for and receiving your hearing aid. How would you rate your feelings about the individual who worked with you? (Check one)

- (a) Satisfied with the individual
- (b) Dissatisfied with the individual
- (c) Neither satisfied nor dissatisfied

14

12. Think about the service you have received from the individual or agency after you received the hearing aid. How do you rate your experiences? (Check one)

- (a) Satisfied with the service
- (b) Dissatisfied with the service
- (c) Neither satisfied nor dissatisfied

23

13. If you needed a new hearing aid today, would you purchase the new hearing aid from the same individual (or at the same place) where you purchased the last one? (Check one)

- (a) Yes
 (b) No

24

14. Think about the total amount that you paid for testing, earmolds, service, warranty and the hearing aids. Did you feel that the total amount that you paid to obtain the hearing aid was: (Check one)

- (a) About right
 (b) Too much
 (c) Did not have to pay for the hearing aid

17

15. What brand (manufacturer) is your hearing aid?

10

16. Who suggested that you obtain a hearing aid? (Check only one)

- (a) No one, it was my idea
 (b) My spouse
 (c) A relative other than my spouse
 (d) A friend
 (e) A physician
 (f) The person I purchased the hearing aid from

16

17. From whom (what professional person) did you purchase your hearing aid? (Check one)

- (a) A hearing aid dealer, hearing aid dispenser, licensed or certified hearing instrument technician
 (b) An audiologist (A person with a Master's degree or doctoral degree certified or licensed as an audiologist)
 (c) A physician (a medical doctor)
 (d) Other _____
 (e) Don't know

12

18. Why did you go to the particular person or agency where you purchased your hearing aid? (Check one)

- (a) Someone recommended it to me
 (b) I responded to an advertisement
 (c) I was familiar with the brand of hearing aid they sold
 (d) The person or agency contacted me
 (e) The agency (or office) was located conveniently to me
 (f) Other _____

11

19. Where did you purchase your hearing aid? (Check one response that best matches where you made your purchase.)

- (a) A physician's office, medical clinic, or hospital
 (b) A place whose only business is the sale of hearing aids
 (c) A drugstore or pharmacy
 (d) A department store such as Sears, Montgomery Ward or J.C. Penney
 (e) A place that sells both eyeglasses and hearing aids, but is not part of another store
 (f) A place that provides other types of hearing testing and rehabilitation services in addition to the sale of hearing aids
 (g) In my home (the person who sold me the hearing aid came to the place where I live)
 (h) From a mail order company
 (i) Other _____
 (j) Don't know

13

20. How did you pay for your hearing aid? (Please check one response that best matches your experience.)

- (a) _____ I paid the entire cost of the hearing aid myself
- (b) _____ I purchased the hearing aid "on time" -- financed the purchase of the hearing aid (credit card, financed by dispensing agency, borrowed money from a lending institution)
- (c) _____ I paid for part of the cost of the hearing aid myself and received financial assistance from an individual
- (d) _____ The hearing aid was paid for or provided by an individual at no cost to me
- (e) _____ I paid for part of the cost of the hearing aid myself and received financial assistance from an agency
- (f) _____ The hearing aid was paid for or provided by an agency at no cost to me
- (g) _____ Other _____

18

21. Which of the following descriptions best match your purchase experience (Check only one).

- (a) _____ I was given a minimum of a 30 day money back guarantee. I could return the hearing aid at any time during the trial period and receive all of my money back.
- (b) _____ I was offered the opportunity to rent the hearing aid for a minimum of a 30 day period. If I decided to keep the hearing aid, the rental price of \$ _____ applied to the purchase price.
- (c) _____ I was given a minimum of a 30 day trial period. If I returned the hearing aid during the trial period I would be charged a fee of \$ _____.
- (d) _____ Other _____
- (e) _____ Don't know _____

20

22. How much did you pay for your hearing aid and the services?
Complete Part A or Part B.

- A. _____ The bill was not itemized, I paid one amount for everything.
\$ _____ Total amount I paid.

Was this amount for 1 or 2 hearing aids? (Circle one)

----- OR -----

- B. _____ Please show the amounts you paid for each service or product which were paid for at different times or itemized separately on your bill. (Leave the item blank if you did not pay for the item or if it was not itemized on your bill.)

- (1) \$ _____ Hearing test
- (2) \$ _____ Hearing aid evaluation
- (3) \$ _____ Hearing aid (price for one hearing aid even if you bought two)
- (4) \$ _____ Earmold (price for one earmold even if you bought two)
- (5) \$ _____ Insurance
- (6) \$ _____ Extended service plan for _____ years.
(Extended warranty)
- (7) \$ _____ Post-fitting visits (Follow-up visits)

25

23A. Did you see a physician for an ear examination before you went to the person who sold you the hearing aid? (Check one)

- (a) Yes.
STOP, you have finished this question,
GO TO QUESTION 24.
- (b) Yes, I purchased the hearing aid at the physician's office.
STOP, you have finished this question,
GO TO QUESTION 24.
- (c) No. **GO TO QUESTION 23B.**

15A

23B. Did the person who sold you the hearing aid advise you that it is in your best interest to see a physician before purchasing a hearing aid? (Check one)

- (a) Yes. **GO TO QUESTION 23C.**
- (b) No. **GO TO QUESTION 23D.**

15B

23C. Did you see a physician as a result of this advice? (Check one)

- (a) Yes.
STOP, you have finished this question.
GO TO QUESTION 24.
- (b) No. **GO TO QUESTION 23D.**

15C

23D. Did you sign a waiver stating that you had been advised to see a physician before purchasing a hearing aid, but you had decided not to do so? (Check one)

- (a) Yes. **GO TO QUESTION 24.**
- (b) No. **GO TO QUESTION 24.**

15D

24. Did your hearing aid have a warranty period? (Check one)

- (a) Yes
- (b) No
- (c) Don't know

21

25. Were you charged a "service fee" for any repairs or changes on your hearing aid during the warranty period? (Check one)

- (a) Yes
- (b) No
- (c) Don't know

19



Hearing Report



Hearing Aids

I don't feel confident to write a letter to AARP in Washington D.C. on the 1st of December 1987, and it can be some time before I do. I have encountered

if I want to hear what is said and had the reception. I would have to find one and pay my own particular amount. You know, I'm not used to do that. I also had the feeling that I was getting short shrift lost standing in a group when I couldn't hear



*Dr. C. Everett Koop
Former Surgeon General of
the United States*

Vol. 1
No. 4

In the beginning, a hearing loss is almost unnoticed and slowly worsens over time.

Introduction

For many older people, this story is familiar. At least eight million adults over age 65 live with an untreated hearing loss. It's often part of aging. In fact, it's the third most prevalent chronic condition for older Americans.

In the beginning, a hearing loss is almost unnoticed and slowly worsens over time. It's not life-threatening, but it can isolate an individual and limit his/her ability to function.

Fortunately, for most people, there's an answer. On December 14, 1987, Dr. Koop went to another

reception. This time, he says, "I could stand upright, talk to people, hear them, and make appropriate responses. The only difference was, [that morning] I got my hearing aids."

This AARP product report is about hearing aids, also called hearing instruments (there are other devices that can assist the hearing impaired that are not included in this booklet). It provides information on the steps to take when buying a hearing aid, as well as product and price information.

AARP encourages the appropriate use of these instruments to treat hearing loss. However, it cautions consumers that buying a hearing aid is not like being fitted with glasses. Even with the best testing and fitting, a hearing aid will not amplify every note at the symphony. Worse, if you're not careful, an aggressive dispenser, using hard-sell tactics (some salesmanship is always involved), could persuade you to buy the wrong instrument or instruments.

What Is a Hearing Aid?

You can still see them in the reruns of silent movies: mechanical hearing aids or ear trumpets with long horns raised to the ear. With microchips, today's hearing aids are miniaturized to fit either behind or in the ear.

A modern hearing aid is an electronic device that picks up sound waves with a tiny microphone, changes weaker sounds into louder sounds (amplifies) and conveys them to the ear through a tiny speaker. A battery powers the electronic

circuitry.

Although body aids (hearing aids the size of a pack of cigarettes) and eyeglass models are still made, almost all instruments sold today are behind the ear (BTE), in the ear (ITE), or in the ear canal (ITC).

Hearing Loss

Disorders in any part of the ear, auditory nerve, or brain can cause hearing loss. They include ear wax build-up, a hole in the eardrum, or a side effect of diabetes or another treatable disorder. Only five to ten percent of adult hearing problems are medically or surgically treatable.

Among older people, hearing loss is most commonly attributed to what's called **presbycusis** (Greek meaning old man, hearing) or the gradual decline of hearing. Only one percent of those under 17 have any hearing loss, but almost 40

percent of those over 75 do. It's also called a **sensorineural** disorder or simply referred to as "nerve damage" or "nerve deafness" by some. There are also conductive (where sound is not fully conducted to the middle ear) and combination (conductive and sensorineural) losses, but these aren't as common.

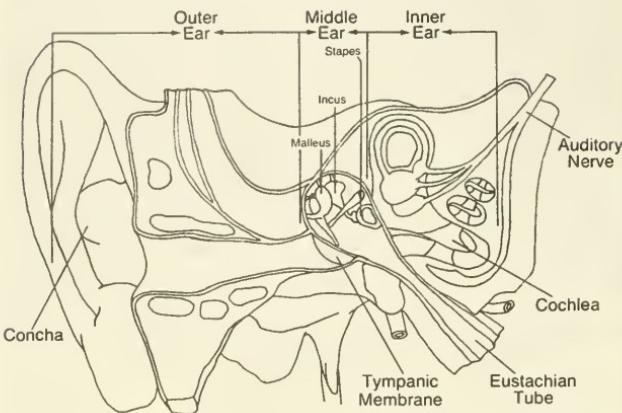
Hearing impairment is measured by the amount or level of loss in what are called decibels (dB) hearing level (HL). Decibels are like degrees on a thermometer. As temperature increases, so do the number of degrees. As the volume of sound

increases, so do the number of decibels. Normal conversation is usually between 45-55 dB. A baby crying hovers around 60 dB and downtown traffic can blister the ear at 90 dB.

If you can hear sounds between 0 and 25 dB HL most of the time, your hearing is normal or near normal and you probably don't need a hearing aid, although it may enhance your abilities in some situations. If you can only hear sounds above 25 dB HL, your hearing loss may be mild, moderate, severe, or profound (see below). Hearing aids are

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Anatomy of The Human Ear



designed, in part, to compensate for the level of loss.

However, hearing isn't just a question of volume. To hearing impaired, sounds can also seem distorted. A frequent comment from older people with a hearing loss is "I can hear you, but I can't understand you."

This happens because hearing losses are usually greater in the higher frequencies (the

pitch) for many older people. That is, traffic noise (low frequency 250 Hz¹) remains as clear as it has always been, but a flute's high notes (9,000 Hz) can barely be heard.

Some consonants, like s, t, f and th are only heard at 4,000 Hz. If you have a loss at 3,000 Hz and above, you can hear words but often can't distinguish between them. This is

called speech discrimination. Merely raising the volume won't necessarily help you distinguish "kit" from "fit" or "cat" from "sat." To compensate, you need a hearing aid to amplify higher frequencies, not all of them.

Hearing impairment is measured by the amount or level of loss in what are called decibels (dB) hearing level (HL).

Level of Loss	Description	Effect	Need for Hearing Aid
0 - 4 dB HL	Mild	Difficult to hear speech	Not needed
4 - 8 dB HL	Mod.	Difficult to understand language	Frequent need
6 - 8 dB HL	Severe	Can't understand amplified speech	Assisted listening, communication
81 dB HL or more	Profound	Difficult to understand amplified speech	May need to supplement with reading, aural rehabilitation, or sign language

¹The frequency of sound is measured in Hertz or Hz.

How to Find a Hearing Health Care Specialist

As with many first-time consumer purchases, you're at a disadvantage in shopping for a hearing aid. You're buying an expensive piece of electronic equipment and you're also selecting a hearing health care specialist. This person uses complex equipment to test your hearing, evaluates your need for an aid, trains you to use it, and provides service during the months ahead. This specialist can be more important than the hearing aid itself, but consumer protections are generally weak.

Before "your fingers do the walking," common sense dictates and federal regulations strongly advise that you visit your doctor first. Sometimes, hearing loss is only a symptom of a treatable problem such as diabetes and a hearing aid can aggravate or mask these medical problems. To bypass this step, which some recommend, is a bad idea. It is best to ignore any advice which suggests that a medical evaluation is not necessary.

In almost all cases, medical/surgical treatment won't help and you will need to begin your search for a specialist. Your doctor may refer you, or friends and neighbors may suggest a specialist. Experience is an excellent in-

dicator of quality service. However, it's still a good idea to shop around; testing procedures and prices vary considerably.

Hearing specialists can be found in the Yellow Pages under "hearing aids" and "audiologists". Large retail chains like Sears and Montgomery Ward also have hearing specialists in some stores. In most cities a variety of professionals can be found, although your choices may be limited in rural areas.

As you page through the di-

rectory, be wary of any claims in the ads—there are no miracle cures. Also, be aware that hearing tests aren't really "free." Their cost is either included in the price of any hearing aid you buy (if you don't buy a hearing aid, you shouldn't be charged), or separately billed.

No matter where you live, your decision will be a trade-off between price and value. As you phone around, AARP suggests you learn as much as you can and refer to the checklist of questions on the next page.

According to the federal Food and Drug Administration (FDA), the following conditions must be met by all dispensers* before selling a hearing aid.

- Dispensers must obtain a written statement from the patient signed by a licensed physician stating that the patient's hearing has been medically evaluated and that the patient is considered a candidate for a hearing aid. This medical evaluation must have taken place within six months of the date of sale.
- Dispensers must advise patients who appear to have a hearing condition to consult promptly with a physician.

The hearing health care specialist can be more important than the hearing aid itself.

Background

One: Which kind of hearing health care specialist do you need?

There are three kinds of hearing specialists: otolaryngologists/otologists, audiologists, and hearing aid dealers (also called hearing instrument specialists). While not every otolaryngologist and audiologist tests and sells hearing

aids, many do.

An otolaryngologist (ear, nose and throat specialist) or otologist (ear specialist) is a physician who provides medical/surgical treatment for hearing disorders. These physicians don't normally dispense hearing aids, but about 70 percent of them have audiologists on staff to test hearing and

dispense hearing aids.

More commonly, audiologists and hearing aid dealers evaluate hearing and dispense hearing aids. Audiologists have a graduate degree in the measurement and treatment of hearing impairment. They are licensed in 38 states and many are certified by the American Speech Language Hearing

*The term "hearing aid dispenser" refers to anyone selling aids, whether a hearing aid dealer, audiologist, or otolaryngologist (see below for a more detailed description).

Association (certified audiologists are designated by the letters CCC-A).

Hearing instrument specialists are licensed in 46 states and the District of Columbia (Colorado, Massachusetts, Minnesota and New York do not currently license dealers) to test hearing and sell hearing aids, accessories, and batteries. While these specialists have less formal education, many have considerable experience. Dealers probably test and fit over half of all hearing aids sold nationwide. In many areas, dealers are the only hearing specialists available.

In most states, there are no formal educational requirements, but all states licensing dealers require that applicants pass an exam (with the exception of Alaska). Some dealers are certified by the National Board for Certification of Hearing Instrument Sciences (certified dealers are designated by the letters BC-HIS). Also be aware that some dealers have inaccurately called themselves "certified hearing aid audiologists."

Two: Is the hearing health care specialist/dispenser reputable?

Most specialists are in business for themselves, although there are hearing and audiological clinics affiliated with universities and hospitals (clinics, while not always convenient, can often provide the best value for your money). Many times, the specialist who tests your hearing also dispenses hearing aids. This delivery system does work, but there's always the chance that a dispenser is pushing a certain brand only to increase his/her income or win additional points toward a trip to Europe (manufacturers in this industry, like others, offer incentives to increase sales).

Over the years, there have been a number of reported abuses in hearing aid sales. For example, the Attorney General of Vermont recently reported consumer problems with the

Hearing Health Care Specialist Checklist

- Which kind of hearing health care specialist do you need?
- Is the specialist/dispenser reputable?
- What's included in a hearing examination?
- How much does the testing cost and can you get the results?
- Is a trial period included?
- Are any follow-up visits included?
- What about service?

prescription of unnecessary hearing aids, with dispenser competency, and with deceptive advertising (Vermont did not license dispensers until 1989).

One way to help protect yourself is to call your local Better Business Bureau (BBB), consumer protection agency, attorney general, or the board which licenses dealers, audiologists, or doctors in your state capital. Find out if there are any complaints on file or a record of actions taken. If there's a pattern of complaints, it's best not to walk in the door.

Another precaution is to find out how long the dispenser has been in business. You want someone who's got a proven track record and who will be around for service over the long haul.

You can also help yourself and other consumers by filing a complaint if you encounter problems with a dispenser. You can complain to the Federal Trade Commission, Food and Drug Administration, your attorney general or consumer protection agency, the state licensing board, or the Better Business Bureau.

Three: What's included in a hearing examination?

There's no single test for hearing; rather there's a battery of tests which measure the extent of hearing loss and the ability to understand speech. There are professional disagreements about testing. For this guide, we list the procedures used by the hearing clinic at Gallaudet University (the na-

tion's university for students with hearing impairment) and the Department of Veterans Affairs (VA).

The testing available in your area may not be as comprehensive. We offer the list below as a yardstick of what you should look for. Generally speaking, thorough testing leads to better fitting and audiologists often provide a more complete exam—more of these professionals use equipment such as real ear measurement, for example.

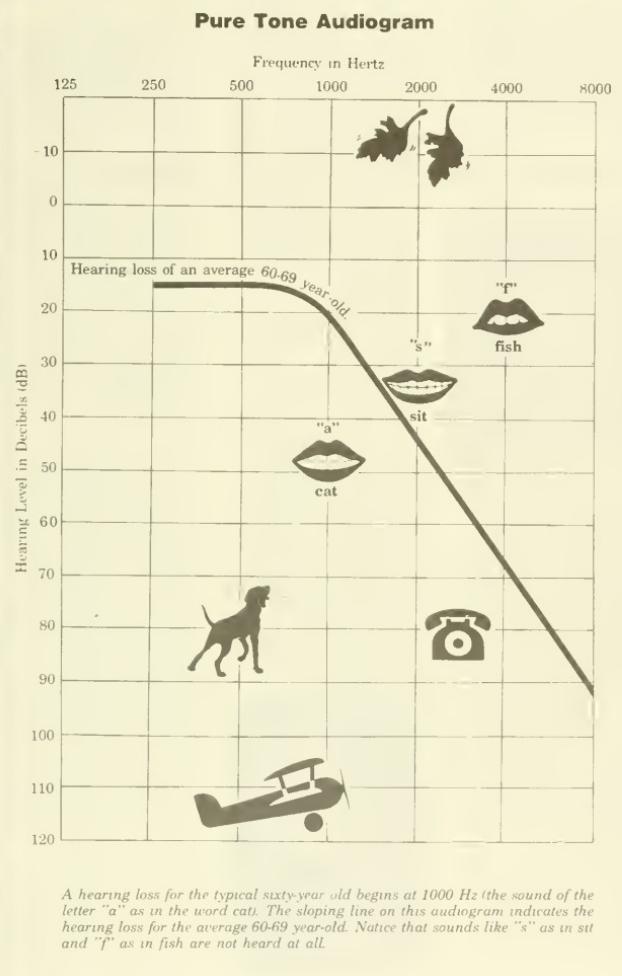
Hearing examinations should include most of the following:

- a "case history" of every client;
- audiometric tests including pure tone air and bone conduction, speech reception and speech discrimination, most comfortable level, and the threshold of discomfort (an audiometer with ear phones is used);
- imittance (or impedance) testing with reflex decay to evaluate outer, middle, and inner ear functions;
- sound field testing using loud speakers rather than ear phones;
- evaluations with product samples or master hearing aids to try out different brands and models; and
- Probe Microphone Real Ear Measurement, where a miniature microphone is placed in the ear canal.

Hearing tests should be conducted in a near-sound proof room, not in your home, a drug store, a church basement, or

There's no single test for hearing; rather there's a battery of tests which measure the extent of hearing loss and the ability to understand speech.

A hearing aid picks up sound waves, changes weaker sounds into louder sounds and conveys them to the ear.



A hearing loss for the typical sixty-year old begins at 1000 Hz (the sound of the letter "a" as in the word cat). The sloping line on this audiogram indicates the hearing loss for the average 60-69 year-old. Notice that sounds like "s" as in sit and "f" as in fish are not heard at all.

Chart Courtesy of Mary Ann Kinsella Meier, Gallaudet University.

even a hotel/motel. There are exceptions to this rule—bed-ridden patients for example—but existing background noise can conflict with good testing procedures. Also, the specialist should almost always be positioned in such a way that you cannot see his lips or observe any motion to ensure a valid test.

Four: How much does the testing cost, and can I get the results?

A complete work-up doesn't come cheap. Gallaudet, which receives federal funds, charges \$105 for its testing and hearing aid evaluation (April 1989) but other clinics and audiologists in private practice may charge as much as \$200 for the same tests. Unlike Gallaudet, many audiologists and most dealers include testing in the price of the aid purchased.

Be sure to ask if there's a separate charge. When testing fees are paid separately, a hearing aid should cost less. Conversely, it should cost more if testing fees are included in the retail price.

Your test results, including speech discrimination results, are recorded on what's called an audiogram, which is also used in recommending an aid. Make sure it's fully explained to you.

Be sure to ask in advance if you can have a copy of your audiogram. Not every specialist provides copies, but it's important in understanding your own hearing loss and for securing a second opinion. If you pay separately for a hearing exam, you should have no trouble securing an audiogram. If testing is part of the retail price, it may be more difficult to secure, but don't give up.

Five: Is a trial period included?

In this expensive purchase, your most potent protection is a trial period. Don't go to any dispenser who doesn't offer in writing a 30-day trial—or better yet, if you can find one—a 60-day trial period.

In fact, hearing aid manufacturers, hearing specialists, and consumer groups all recommend—and state laws in Alaska, Colorado, Connecticut, the District of Columbia, Kentucky, Maine, Oregon, Vermont, Tennessee, Texas, Washington, and West Virginia require—that consumers be given at least a 30-day trial period (45 days in Vermont) with only a small service fee (varying from five to 20 percent of the purchase price) in case of a return.

Returning an aid doesn't mean giving up. It means modifications are needed or that a particular aid didn't work for you. Many users succeed only after modifying or trying a different hearing instrument. For example, one of the largest purchasers, the VA, requires modifications, many of which are minor, on 50 percent of the hearing aids they fit.

The trial period should be fully explained to you before hand, including the amount of service charges owed in case of a return. Ask before you visit. If the service fee is excessive, take your business elsewhere. The Attorney General of Vermont is currently suing a dispenser there for charging more than state law permits. Manufacturers routinely make modifications and permit hearing aid returns within 60 to 90 days at no charge to the dispenser.

Also, be sure you're counting the right 30 or 60 days (calendar or working days) and be wary of delays for repairs or adjustments. Will a dispenser's minor adjustments eat up any of your trial period, for example?

Six: Are any follow-up visits included?

While some people can simply put on a hearing aid and walk out the door, almost all new users require training and help with adjustments. Some dispensers charge extra for this. Others include one or more return visits in the purchase price.

You should also ask if the dispenser offers what's called aural rehabilitation or, if the answer is no, where it might be available and how much it costs. Aural rehabilitation is extremely helpful and can include special sessions to train users and their spouses to listen in a new way using visual clues such as lip movements, facial expressions, and others. It's estimated that as much as 40 percent of hearing is visual and the most difficult consonants to hear are frequently the easiest to lip-read.

Seven: What about service?

According to the VA, hearing aids should last at least four years, although changes in your hearing may require you to buy a new one before that. Many hearing aids last much longer if properly cleaned and maintained. But repairs and adjustments are needed from time to time—a hearing aid is a delicate instrument subject to constant use. Volume controls, for example, do break down.

Dispensers will make adjustments and minor repairs. But for major repairs, hearing aids are usually returned to the factory, whether or not they're under warranty. Consumers need to know what the turnaround time is. Also, does the dispenser offer loaner aides to tide you over?

There are three kinds of hearing specialists: otolaryngologists, audiologists, and hearing aid dealers (also called hearing instrument specialists).

What Kind of Aid?

With an audiogram in hand, your next question is, what kind of aid? Here the specialist's opinion is very important. He/she should have the skills and training to prescribe an aid that matches your loss. But remember, an informed consumer should be part of the entire process. Don't hesitate to ask questions and express your concerns. To assist you, we've included a checklist (page 9) of questions to ask and examples of different hearing aids.

AARP advises you seek a second opinion about any recommended aid from a different dispenser—fitting is more an art than a science. In some instances you'll be able to secure a second opinion based on your audiogram. In other instances a second dispenser will retest you. But remember, you shouldn't pay for testing more than once. Compare price and value.

Manufacturers don't set retail prices (dispensers do) and you may find the same hearing aid costs \$300 less just across town. But cost shouldn't be your only consideration. As in all purchases, there are trade-offs, but the price you pay is always important.

If the second dispenser recommends a different model, sample the two hearing aids yourself; if you can—master hearing aids and sample instruments facilitate this. It's likely that any instrument will increase your hearing to some degree, but which one works best for you? Only you can answer that question.

Background

One: Which brand and model should you consider?

Brand names—There are some 40 manufacturers (some dispensers even assemble hearing aids in their offices), but the top ten companies account for the overwhelming majority of all hearing aids sold. Most hearing aids use similar elec-

tronic parts. The differences between brands are in their circuitry, workmanship, special features and policies regarding warranties and services.

With some products, the electronic circuitry for each model is fixed. With others, the body of the hearing aid doesn't change, but the dispenser or the manufacturer installs circuitry to match your audiogram or the results of special testing.

Most of the larger manufacturers make BTE, ITE, and ITC hearing aids, although some only make custom hearing aids (ITEs and ITCs). Most dispensers offer a number of different brands, but there are exceptions. For example, Beltone, and Miracle Ear (Dahlberg, Inc.) hearing aids are only available from authorized dispensers. Sears, too, only dispenses an aid carrying its label, but Dahlberg is the manufacturer.

Later in this guide, you will find examples of hearing aids manufactured by different companies.

Models—Over 98 percent of the hearing aids sold today are BTEs, ITEs, or ITCs. Choosing a model which meets your needs depends upon a variety of factors such as size, power, ease of use, and cosmetic appeal.

BTE hearing aids are two-inch-long crescent-shaped devices that hook over your ear. A

small tube connects the hearing instrument with a custom ear mold. It comes equipped with an adjustable volume control, usually a ridged knob in the center of the crescent. The battery slips into a compartment at the bottom of the aid. The BTE's larger size permits the use of larger components that enable it to provide more power and features.



ITEs are one-piece instruments, custom fitted to the contours of your ear. No tubes or cords are needed because the miniature speaker is already in the ear.

The volume control is the raised wheel. A battery is usually fitted into a swing-out shelf. Both the volume control and the battery compartment are, by comparison, much smaller than a BTE.

The smaller size limits its output somewhat, but more significantly, it can create difficulties for some users inserting or removing the instrument, changing the tiny batteries or adjusting the volume control. There are modifications such as fingernail notches or handles for inserting and removing the instrument, a raised volume knob, or a magnetized rod to help slip the battery into place. Test these features yourself to make sure you can use the smaller instrument.



You may find
the same
hearing aid
costs \$300 less
just across
town.



ITCs, or canal hearing aids, are even smaller. These instruments are made to fit in your ear canal and are barely visible—former President Reagan wears an ITC. However, the smaller size further limits these hearing aids. The ITC is cosmetically appealing, but make sure you can manipulate it and that it meets your needs before you buy.

While all hearing aids have breakdowns, ITEs and ITCs seem to require more repairs because of their size. Malfunctions occur in two particular areas, volume controls and wax blockage. Because they're constantly adjusted, volume controls in all hearing aids are vulnerable, but custom hearing aids seem to have more problems than BTEs.

The major weakness of these hearing aids, however, is the potential for ear wax damage. Remember, a custom aid sits in your ear canal for up to 12 hours a day. Proper maintenance is one answer. Another may be the new wax traps or special techniques offered by a number of manufacturers.

Two: Which hearing aid works best with your hearing loss?

Of the three, BTEs are the most versatile. They can be used with mild and moderate hearing losses, and for the severely impaired, it's the aid of

choice. ITEs are prescribed for the same kind of losses but are somewhat more limited because of size. ITCs, on the other hand, usually work with only mild or moderate losses.

There are other factors, however. Our outer ears are designed to focus and direct sound to the inner ear. Canal and ITE hearing aids take advantage of this natural focusing ability. This can compensate for part of their size limitations.

In addition, some canal aids are made with flexible plastic (soft shells). Manufacturers claim these products can be inserted closer to the ear drum than hard shell products. By bringing the hearing aid closer to the ear drum, less power is needed for the same volume, according to these manufacturers.

Three: What special features are available?

There are a variety of special features that enhance an aid's performance or tailor it for certain needs. Generally, the larger size of BTEs enables manufacturers to offer more features. ITEs are somewhat more limited and ITCs offer very few.

Some of these features include:

- **automatic gain control** and **gain control** to reduce amplification in noisy surroundings;
- **automatic signal processing** and **noise blockers**, **feedback controls** and **user operated noise suppression switches** to block or filter background noises and feedback (high pitched squealing sounds) and enhance other sounds;
- **push-pull circuitry** to provide more power in certain circumstances;
- **telecoil circuitry** (**T-switch**) or **direct audio input (DAD)** to directly or indirectly connect a telephone, TV, radio, stereo, or special listening system to the aid; and

- **tone controls** for high and low tones (usually adjusted by the dispenser)

Some hearing aids are programmable (PHOX for example), meaning they're custom programmed to reduce certain noises and strengthen others. 3M's MemoryMate is programmed with up to eight different memories and the Widex Quattro with four memories to match different hearing situations—e.g., noisy rooms with background noises, quiet listening. The user adjusts both the volume and the memory to match the listening environment.

These features also increase costs. For example, automatic signal processing, when available, costs approximately \$100 more and the 3M aid carries a suggested retail price of \$1500.

Telecoil circuitry, which is highly recommended, may cost \$50 more when available (canal hearing aids do not currently offer telecoil circuitry).

Another feature used with many hearing aids are "vents". These are tiny holes in the aid which equalize pressure—so you don't feel like you're listening in a barrel. They also have the effect of reducing certain sounds. A larger vent hole, for example, can reduce unwanted lower frequencies.

Some of these features are already built into the aid. Others are added. Be sure to discuss special features with your specialist. You may be able to sample an instrument that includes one or more of these features during your evaluation.

Four: Which batteries are used and how much do they cost?

Further reductions in hearing aid size and improvements in sound reproduction are currently limited by battery technology, even though tremendous improvements have been made during the last decade.

There are four different sizes of batteries for custom and BTE hearing aids (# 10A/230, 312,

Choosing a model which meets your needs depends upon a variety of factors.

In almost every instance, the cost of a hearing aid must be borne solely by the buyer.

Hearing Instrument Checklist

- Which brand and model should you consider?
- Which aid works best with your hearing loss?
- What special features are available?
- Which batteries are used and how much do they cost?
- What's the frequency response of the aid?
- What kind of warranty is offered?
- How much does it cost?

13 and 675). There are also two different kinds of batteries, zinc air and mercury.

While initially more expensive, zinc air batteries last longer and are actually cheaper if you can use them. Mercury batteries, on the other hand, provide more power and are unaffected by humidity. Three four-packs or 12 zinc air batteries cost about \$12. Three four-packs of mercury batteries sell for around \$10. By shopping around, you can find cheaper rates or join a battery club.

Be sure to ask your dispenser how to dispose of your used batteries properly.

Five: What's the frequency response of the hearing aid?

Advertisements for the best stereos hype the fact that they have a frequency response of 0 to 20,000 Hz, meaning they can reproduce any sound audible to the human ear. Hearing aids, on the other hand, are limited to a range of 200 to 6,000 Hz, although a few claim to go as high as 10,000 Hz. The limitations are technical in nature. For the listener, the limited frequency response means the timbre or quality of sound is reduced.

Generally, you want a frequency response that compensates for the hearing loss indicated in your audiogram. With most users, the dispenser will recommend an aid that matches your loss, but you may want to sample different hearing aids in your evaluation.

Six: What kind of warranty is offered?

Almost all hearing aids carry a one- or two-year warranty for defects in materials and workmanship. Most warranties don't cover earmolds, cords or tubing, or damage caused by improper care or an accident (dogs and cats seem to love to chew ITEs, ITCs, and the ear molds for BTEs). Read over the warranty and make sure you understand it. For example: What parts and repair are included? What will you have to do to get repairs under the warranty? And, What other conditions or limitations are placed on the warranty?

In addition, manufacturers and dispensers offer loss and damage protection or insurance for added coverage. This costs approximately \$75-100 per year and covers a newly purchased instrument for at least two

years. Under this coverage, your aid will be replaced if lost or damaged. Repairs or replacement are usually good for one time only. Read the policy thoroughly before you buy. Some manufacturers include loss and damage coverage in the price of the hearing aid.

Seven: How much does it cost?

In almost every instance, the cost of a hearing aid must be borne solely by the buyer. Neither Medicare nor most insurance policies pay for hearing aids or examinations. Only Medicaid in about half of the states and the VA, when the hearing loss is service-related, will pay for hearing instruments.

The most expensive models are the micro-miniature canal aids. Their average 1988 price was a little over \$700 (including testing and fitting), although they can cost as much as \$1200. BTEs and ITEs averaged about \$550 (including testing and fitting). Remember though, special features can add to this cost and shopping around could save you several hundred dollars (dispensers in the District of Columbia and Vermont are required to post pricing information).

The wholesale to retail mark-up can be as much as three to four hundred percent (the manufacturers' mark-up can also be very high). Dispensers argue this mark-up is not excessive. They're simply passing on costs for rent, utilities, advertising and service to the consumer both before and after the purchase. Consumer advocates, on the other hand, argue hearing aid prices are "excessively high."

Samples of Brand Name Hearing Aids

Literally hundreds of different hearing aids are offered to the public, with new models coming on the market every year. For space considerations, we couldn't include all hearing instruments in this guide.

Below you will find three charts listing BTE, ITE, and ITC hearing aids. Fifteen different brand name instruments are included. These listings are designed to provide you with the names and specifications of

products in the marketplace. They don't indicate an endorsement or recommendation by AARP. They are included for your information only.

**Literally
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aids are offered
to the public,
with new
models coming
on the market
every year.**

BTE Hearing Aids

Brand and Model	Hearing Range	Frequency ³ Response	Features ⁴	Range of Cost
XM-Merry-More	mild to severe	warbles with memory selected	automatic gain control; T-switch up to eight programmable memories, tailored to user and different hearing environments	\$1300-\$2300
Oticon E-fit	mild to severe	16-5600 Hz	automatic gain control, feedback control, noise suppressor switch, T switch; tone control	\$300-\$700
Phon-P-4	moderate loss	varies with programming	automatic gain control, programming to meet user's hearing loss, switch, tone control, T switch	\$700-\$1100
Resound Micro Primo Plus	mild to moderately severe	170-4800 Hz	automatic gain control and protection, T switch, tone controls (high and low)	\$800-\$850
Sears XL	mild to moderate loss	16-42-62	automatic gain control, high frequency aid, T switch, tone control	\$825

Note: AARP does not endorse or recommend any of the above hearing aids. They are included to present samples of BTE instruments sold in most areas of the country. The hearing aid that works best for you may not be included in this chart.

³Frequencies amplified by aid.

⁴Features may be standard or optional depending upon the brand and model selected.

The future may even bring hearing aids that return hearing to "20/20," like eyeglasses do to sight.

ITE Hearing Aids

Brand and Model	Hearing Range	Frequency Response	Features ^b	Range of Cost
Maico FPR	mild to severe loss	270-6000 Hz	automatic signal processing, ALGO, F.R.A., feedback control, push-pull circuitry, T-switch, tone control	\$350-\$800
Mitsubishi Ear AS	mild to severe loss	200-7500 Hz	T-switch, tone control	\$600-\$1000
Siemens 90T	mild to severe loss	120-5000 Hz	automatic gain control, feedback control, push-pull circuitry, T-switch, tone control	\$600-\$700
Starkey CE-7	mild to severe loss	varies with circuit installed	automatic gain control, automatic noise suppression, Adaptive Compression, feedback reduction, T-switch, tone control	\$550-\$700
Telex 2* A	mild to severe loss	varies with circuit installed	automatic gain control, automatic noise suppression, Adaptive Compression, feedback reduction, T-switch, tone control	\$540-\$700

Note: AARP doesn't endorse or recommend any of the above hearing aids. They are included as representative samples of ITE instruments. If most any hearing aid is available, the hearing aid that works best for you may not be included in this chart.

^bFeatures may be standard or optional depending upon the make and model selected.

ITC Hearing Aids

Brand and Model	Hearing Range	Frequency Response	Features ^a	Range of Cost
Acousticon 1000	as low as 1000 Hz	2000-4000 Hz	Automatic signal recognition mode; back channel ASR mode	\$675-\$800
Acousticon 1000	as low as 1000 Hz	2000-4000 Hz	Feedback cancellation; true control system	\$700-\$800
Acousticon 1000	as low as 1000 Hz	2000-4000 Hz	Automatic signal processing; directional microphone; dual feedback cancellation; high frequency emphasis; tone control	\$700-\$800
Quinton 1000	as low as 1000 Hz	2000-4000 Hz	push-pull	\$650-\$800
Acousticon 1000	as low as 1000 Hz	2000-4000 Hz	ear tip; directional microphone; push-pull; physical diagnosis procedures involve consumer	\$700-\$800
Acousticon 1000	as low as 1000 Hz	2000-4000 Hz	ear tip; directional microphone; push-pull; physical diagnosis procedures involve consumer	\$700-\$800

Note: AARP does not endorse any one model of the above hearing aids. They are included, however, to give you a sense of the range of ITC hearing aids available in terms of the cost of the hearing aids that work best for you may not be included in this chart.

An increasing number of hearing aid sales are for two hearing aids or what's called a binaural fitting.

One Aid or Two?

An increasing number of hearing aid sales are for two hearing aids or what's called a binaural fitting. If the hearing loss is significant for both ears, it's important to have an aid in each ear, particularly for capturing sounds on both the right

and left sides. Two aids can also help you hear better in noisy surroundings. Both Dr. Koop and former President Reagan wear two hearing aids, for example.

Be aware, however, that you could pay as much as \$1500-

2000 for two hearing aids although dispensers should discount the second instrument (your hearing is only tested once, even with two aids). Some have also been known to recommend two hearing aids, when only one is needed.

What Should You Hear?

It's difficult to say how much improvement you will notice with your first aid—Dr. Koop noticed a dramatic improvement, but not everyone will. Discuss any problems you have with the specialist who sold you

the aid. If the problems are not corrected, return the aid. Some of the questions you should ask are:

- Is your hearing improved?
- Does the aid fit properly?
- Does it physically hurt?

- Is the sound too loud at times?
- Is there an echo or do you feel like you're listening in a barrel; and,
- Is the sound tinny?

^aFeatures may be standard or optional depending upon the make and model selected.

A successful fitting comes down to you, the user.

Adjustment to the Hearing Aid

You may also hear background noises—the sound of a fan motor or fluorescent lights—amplified much louder than you remembered. All of these will require adjustments on your part as a user. You may also benefit from aural rehabilitation.

Finally, a successful fitting comes down to you, the user. A specialist can work with you to help you learn how to insert,

remove and adjust the aid and to cope with a new way of hearing. You'll be evaluated with the aid on watching television, listening to music, or simply listening to conversations in the office for several hours. All of this is part of the adjustment process.

A schedule of listening with the aid is also established for a specified time period. Return visits may or may not be estab-

lished at the same time. If the aid doesn't fit your needs, return it within the trial period!

The dispenser should also advise you about care and maintenance. For example, he/she will suggest you keep your hearing aid dry and avoid temperature extremes. Also, hard knocks and hair spray will damage the instrument.

The Future of Hearing Technology

It's only going to get better. Changes in hearing aid technology will be significant over the next few years and should benefit consumers.

For example, digital hearing aids are coming on the market. These hearing aids are pre-programmed to delete certain kinds of sounds and are variable to meet the needs of different users in different hear-

ing situations. Currently, they're only available as body aids because they require more power. Over time, they'll be improved and miniaturized.

Researchers are also experimenting with implantable hearing aids that are surgically placed in the middle ear. The Resound hearing aid, which is soon to enter the market, takes a middle path. The instrument

is a canal aid, but minor surgery is required to widen the ear canal for deeper insertion.

Beyond digital and implantable hearing aids, consumers can look forward to better testing and fitting, and hearing aids that are more versatile. The future may even bring hearing aids that return hearing to "20/20," like eyeglasses do to sight.

Conclusion

For the hearing impaired, a hearing aid can be a lifesaver, permitting users to communicate again. Far too many older Americans deny their hearing loss and limit their lives.

Dr. Koop began wearing hearing aids at the age of 71. He recommends:

- Don't be ashamed of your hearing loss;
- Don't be ashamed to get help;
- Don't be ashamed to wear a hearing aid; and,
- Be sure the person you live with goes through training with you so that you're both blaming the right things for any failures.

Good advice from the former Surgeon General. AARP also recommends you shop carefully

and wisely, take the full battery of hearing tests, attend training classes, and exercise your rights during the trial period, if needed.

Other resources

Another AARP booklet on hearing loss is called *Have You Heard? Hearing Loss and Aging* (D12219). It's available by written request (postcard) from AARP Fulfillment, 601 E Street, NW, Washington, DC 20049.

Federal Trade Commission
Washington, DC 20580

Food and Drug Administration
Office of Consumer Affairs

HFE-88
5600 Fishers Lane
Rockville, MD 20857

American Speech-Language-Hearing Association
10801 Rockville Pike
Rockville, MD 20852

National Hearing Aid Society
20361 Middlebelt
Livonia, MI 48152

National Information Center on Deafness
Gallaudet University
Kendall Green
800 Florida Ave. NE
Washington, DC 20002

Self Help for Hard of Hearing People
7800 Wisconsin Ave.
Bethesda, MD 20814

APPENDIX 2

Suggested Questions for Witnesses at Aging Committee Hearing**Dr. Margaret Dixon, Vice President, AARP**

Q: Am I correct in understanding that the AARP sells hearing aids through its pharmacies?

AARP does not, but the AARP Pharmacy Service, a separate corporation, does. As stated in the introduction to the AARP report submitted to the committee (A Report on Hearing Aids), "The AARP Pharmacy Service leases space in three of its pharmacies to a provider who evaluates and fits hearing aids. Sales in 1992 were significantly less than one half of one percent of the hearing aid market." The name of that provider is HearX.

Q: If so, can you tell me if people who bought hearing aids through the AARP were any more or less satisfied than other respondents to your consumer survey?

Of the 4,000 letters we evaluated, we found no letters from users who had purchased their aid from an AARP pharmacy. This is not surprising given the relatively small number of aids dispensed in the three pharmacies.

Q: In your written testimony, you recommended that a 30-day return period should be required for the sale of all hearing aids. Do AARP pharmacies have such a policy and, if so, do they make sure that customers are fully informed that they have the option of returning the hearing aid within 30 days?

HearX provides a 30-day return policy to every person purchasing a hearing aid. If the purchaser attends and completes a free-of-charge post-fitting rehabilitation course of four one hour sessions, the return policy is extended an additional 30 days or 60 days in total. The fee for a return totals \$50 for a single aid and \$65 for dual aids.

The return policy is discussed with the purchaser and is outlined in the contract.

Q: What type of "hearing evaluation" should a customer expect to receive at an AARP pharmacy? Are these evaluations always performed by a certified audiologist -- as you recommend in your testimony?

A licensed, certified HearX audiologist performs the following battery of tests with each "hearing evaluation":

- o An Otoscopic Examination
- o Tympanometry
- o Stapedial Reflex Thresholds
- o Pure-Tone Audiometry (Air and Bone Conduction)
- o Speech Audiometry
- o Speech Reception Threshold
- o Word Discrimination Scores
- o Comfort Levels

Q: When the AARP asked its members to provide "consumer feedback" on hearing aids in the September 1991 issue of AARP Bulletin, was this done in such a way as to elicit responses from all readers or only from those who were dissatisfied?

The questions were designed to be neutral. However, you can judge for yourself the neutrality of these questions. The article eliciting the consumer letters is attached. It can also be found on page 79 of the report.

Q: Can you tell me anything about the nature of the responses the AARP received from my home state of Wyoming? Did the results differ very significantly in different regions of the country?

Out of the 4,000 letters tabulated, we received a total of nine (.2 percent) letters from hearing aid users in Wyoming. Unfortunately, that number is too small to perform any statistical analysis.

Based on a recent analysis, there are regional differences (see chart below).

Zip Code Areas and States	Positive	Negative	Both
O or 1 NY, MA, RI, VT, NH, ME, CT, NJ, Puerto Rico, APO	41%	33%	25%
2 or 3 DC, MD, VA, WV, NC, SC, GA, FL, AL, MS, TN	45%	35%	20%
4 or 5 KY, OH, IN, MI, IA, NE, WI, MN, SD, ND, MT	39%	32%	29%
6 or 7 IL, MO, KS, NE, LA, AR, OK, TX	46%	33%	21%
8 or 9 CO, WY, ID, UT, AZ, CA, HI, OR, WA, AK	40%	37%	24%

Q: In your written testimony, you stated that only 3.78 million Americans wear hearing aids, but that there are estimated to be 23.5 million Americans with hearing loss. It seems to me that it would be very difficult to make such an estimation unless these people have actually received hearing evaluations. How was the figure of 23.5 million arrived at? Is it based on sound medical evidence or is it mostly speculation?

The source for the 23.5 million figure is a hearing industry study called MarketTrack. This study is widely accepted within the industry as a statistically valid survey using members of the National Family Opinion Panel (NFO). The study (actually there were three separate studies) is footnoted and mentioned in the Bibliography to the report under the name of Kochkin.

There are other estimates for the number of persons with a hearing loss. For instance, the October issue of the *New England Journal of Medicine* (Nadol, Joseph B., Jr. M.D. "Hearing Loss") reports, "It has been estimated that more than 28 million Americans have hearing impairment and that as many as 2 million of this group are profoundly deaf."

The National Center for Health Statistics conducted an interview survey in 1990 to ascertain the level of speech and hearing impairment. Their estimate is 22.6 million Americans have a hearing loss. (Adams, P.S., Benson, Z. "Current Estimates from the National Health Interview Survey." Vital and Health Statistics, Series 10, Vol 184, (1992). National Center for Health Statistics.)

While we did not analyze the specific questions or inquire about the methodologies used, there seems to be a general agreement that the level of hearing loss in our population is in excess of 22 million people.



RETIRED PERSONS SERVICES, INC.

Brian S. Frid
President & CEO

October 20, 1993

Dr. Margaret Dixon
Vice President
AARP
601 E Street, N.W.
Washington, D.C. 20049

Dear Margaret:

It was a pleasure being together at last week's Board Committee on Membership and Member Services meeting. I, Brian Frid, enjoyed it and hope the information provided is useful, and look forward to speaking about the Pharmacy Service activities at any time.

Since then, I have received copies of a request for response from Senator Simpson, who was unable to attend the hearing at which you testified. To the extent that we can be useful in framing the responses, I am providing the following that I hope will be helpful.

Question #1

Lee Norgard, with whom I have been in contact, will address the detail in Question #1, but I want to add to his appropriate response. Of course, AARP does not sell hearing aids; nor does the AARP Pharmacy Service, directly.

We do have a relationship as landlord with a hearing service provider, HearX (tenant). HearX leases space at three of our facilities:

1. Portland, OR
2. Richmond, VA
3. St. Petersburg, FL

Just so there is no confusion, I do want you to know that the Pharmacy Service does sell hearing aid batteries.

500 Montgomery Street
Alexandria, Virginia 22314-1563
(703) 684-0244 Fax: (703) 684-0246

The Pharmacy Service of the American Association of Retired Persons

Margaret Dixon
October 20, 1993
Page Two

Question #3

It is the policy of HearX to provide a 30-day return policy to every person purchasing a hearing aid. In addition, if the individual takes and completes a free-of-charge rehabilitation course consisting of four one hour sessions, the return period is extended an additional 30 days.

It should be noted, however, that varying state laws do provide for a portion of the price charged to be retained by the dispenser in the event of a return. This amount is provided to cover some of the costs associated with the testing, evaluation, and fitting (molds) of the unit. This totals \$50 for a single aid and \$65 for dual aids, in the event of a return to HearX at each of our locations.

On the attached documents, you can see for yourself where I have circled the applicable provision.

Question #4

The following "hearing evaluation" is provided at no-charge and performed by a licensed/certified audiologist employed by HearX:

- OTOSCOPIC Examination
- TYMPANOMETRY
- STAPEDIAL REFLEX THRESHOLDS
- PURE-TONE AUDIOMETRY (Air + Bone Conduction)
- SPEECH AUDIOMETRY
- SPEECH RECEPTION THRESHOLD
- WORD DISCRIMINATION SCORES
- COMFORT LEVELS

Question #7

As I said, we are not directly in the business (HearX is a tenant) and although not an expert in this area, I thought you would be interested in information provided to us by HearX referencing the New England Journal of Medicine in which they state there are over 28 million hearing impaired.

Please contact me personally if I can be of any future assistance in this or any other matter.

Sincerely,



Brian S. Frid

cc: Bob Venafro

Enclosures

*Your Prescription for Better Hearing***ONE YEAR****WARRANTY**

provides you with a one-year consumer protection plan on your hearing aid sold through a center. The policy is as follows:

- Your hearing aids are covered by a limited warranty against defects in workmanship for a period of twelve (12) months from the original fitting date of the hearing aid. All costs associated with the repair of the hearing aid will be at expense, as long as the repair is done through a center and damage is not due to the consumer's gross negligence.
- Within the first thirty (30) days of purchase, the consumer may return the hearing aid to for a refund of the original price, less the cost of \$10.00 for one hearing aid and \$25.00 for two hearing aids.
- Should the consumer successfully complete Education and Learning Program (HELP), which is offered at no charge, will extend the trial period for an additional thirty (30) days and waive any and all non-refundable monies should the hearing aid be returned within this sixty (60) day period.
- If the consumer should be informed by a "participating" physician within the first sixty days of purchase that the hearing aid is inappropriate, will refund to the consumer the total purchase price.
- If a loaner aid is required due to repair of the originally purchased aid, the loaner will be provided at no cost.

*Your Prescription for Better Hearing***TWO YEAR****WARRANTY • 3M PROGRAMMABLE**

provides you with a two year consumer protection plan on your hearing aid sold through a center. The policy is as follows:

- Your hearing aids are covered by a limited warranty against defects in workmanship for a period of twenty-four (24) months from the original fitting date of the hearing aid. All costs associated with the repair of the hearing aid will be at expense, as long as the repair is done through a center and damage is not due to the consumer's gross negligence.
- Within the first thirty (30) days of purchase, the consumer may return the hearing aid to for a refund of the original price, less the cost of \$50.00 for one hearing aid and \$100.00 for two hearing aids.
- Should the consumer successfully complete Education and Learning Program (HELP), which is offered at no charge, will extend the trial period for an additional thirty (30) days and waive any and all non-refundable monies should the hearing aid be returned within this sixty (60) day period.
- If the consumer should be informed by a "participating" physician within the first sixty days of purchase that the hearing aid is inappropriate, will refund to the consumer the total purchase price.
- If a loaner aid is required due to repair of the originally purchased aid, the loaner will be provided at no cost.

**TWO YEAR HEARX EXTENDED WARRANTY PROGRAM
IN-TOUCH HEARING AIDS**

provides a two-year consumer protection plan on your hearing aid sold through center. The policy is as follows:

• Your hearing aids are covered by a limited warranty against defects in workmanship for a period of twenty-four (24) months from the original fitting date of the hearing aid. All costs associated with the repair of the hearing aid will be at expense, as long as the repair is done through a center and damage is not due to the consumer's gross negligence.

• Your hearing aids are protected against loss for a period of twelve (12) months from the original date of purchase. Only one hearing aid will be replaced during this time period. Should the hearing aid be lost during the second year of ownership or if the hearing aid is lost a second time during the first year, will replace the hearing aid at the current published retail price less 50%.

• Should your hearing loss change sufficiently to warrant the use of a different hearing aid during the first twenty-four (24) months of ownership, will provide a new aid at no cost to the consumer.

• Within the first thirty (30) days of purchase, the consumer may return the hearing aid to for a refund of the original price, less the cost of \$50.00 for one hearing aid and \$65.00 for two hearing aids.

• Should the consumer successfully complete Education and Learning Program (HELP), which is offered at no charge, will extend the trial period for an additional thirty (30) days and waive any and all non-refundable monies should the hearing aid be returned within this sixty (60) day period.

• If the consumer should be informed by a "participating" physician within the first sixty days of purchase that the hearing aid is inappropriate, will refund to the consumer the total purchase price.

• If a loaner aid is required due to repair of the originally purchased aid, the loaner will be provided at no cost.

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** TOTAL PAGE. 012 8*

PAGE 205

INVOICE

<input checked="" type="checkbox"/> Private Pay <input type="checkbox"/> Insurance		DATE	CENTER #	OR21	INVOICE #	21	0587	CUSTOMER #
					C/ONAL SECURITY #			
ADDRESS					INSURED BY			
CITY/STATE					POLICY #			
TELEPHONE #					DATE SUBMITTED			
MAKE/MODEL		EAR <input checked="" type="checkbox"/>	STATUS <input type="checkbox"/>	SERIAL #	HEARING INSTRUMENT(S)		AMT. CHG'd 3030	
MAKE/MODEL		EAR <input type="checkbox"/>	STATUS <input type="checkbox"/>	SERIAL #	EARMOULD(S)		3048	
DESCRIPTION OF PRODUCT(S) SOLD:					TESTING FEE		3100	
					OTHER/CO-PAYMENT			
							4318	
					SUB-TOTAL			
					INC PAYMENT			
					TOTAL DUE			
					LESS DOWN PAYMENT			
					BAL. DUE UPON DEL.			
MINIMUM FINANCE OR CHARGE — \$95.00								
DOWN PAYMENT BT:								
<input type="checkbox"/> CASH <input type="checkbox"/> CHECK <input type="checkbox"/> MC/VISA <input type="checkbox"/> AMEX					DATE		LESS PAYM'T AT DELIVERY	
DELIVERY PAY BT:					DATE		BALANCE DUE	
<input type="checkbox"/> CASH <input type="checkbox"/> CHECK <input type="checkbox"/> MC/VISA <input type="checkbox"/> AMEX <input type="checkbox"/> INSURANCE								

LIMITED WARRANTY INFORMATION

The hearing aid you have purchased is covered by a limited warranty offered by _____ for a period of _____ months.
 A separate _____ year limited warranty has been included.

The terms of the limited warranty, including exclusions therefrom, and set forth on a separate form which was delivered to you prior to your purchase. In consideration of the limited warranty referred to above, except as may be set forth therein, MAKES NO WARRANTIES OF ANY KIND, EITHER EXPRESS OR IMPLIED.

Examinations, tests and other representations are non-medical and for the sole purpose of fitting hearing aids.

A HEARING AID WILL NOT RESTORE NORMAL HEARING, NOR WILL IT PREVENT FURTHER HEARING LOSS.

WAIVER

It is desirable that a person seeking help with a hearing problem (especially for the first time) consult an ear doctor and obtain a clinical hearing evaluation. Although hearing aids are often recommended for hearing problems, another form of treatment may be necessary.

I am over the age of 18 and have been advised by HEAfa that the Food and Drug Administration has determined that my best health interest would be served if I had a medical evaluation by a licensed physician (preferably one who specializes in diseases of the ear), before purchasing a hearing aid. I do not wish a medical evaluation before purchasing a hearing aid.

SIGNATURE OF PROSPECTIVE HEARING AID WEARER

LICENEE NAME	LICENEE NUMBER	CUSTOMER SIGNATURE
--------------	----------------	--------------------

71014/SE/73 DISTRIBUTION #: Part: #1-WHITES / Part#: #2-YELLOW / Accounting when delivered: #3 PINS / Accounting when ordered: #4 GOLD / Part#: #5

OCT 19 '93 15:24

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COMPLAINTS REGARDING ANY MATTERS CONCERNING THE HEARING AID OR AIDS SHOULD BE HANDLED BY ONE OR MORE OF THESE METHODS:

1. Contact hearing aid firm or consultant that sold the aid.
2. If a complaint still exists, write the Oregon Hearing Aid Society, P.O. Box 15, Portland, Oregon 97207, or call 228-2839, collect calls encouraged.
3. If complaint still exists:
Complaints regarding the sale, lease, or attempted sale or lease of hearing aids should be directed in writing to: Hearing Aid Dealer Licensing, Oregon State Health Division, 780 Front Street, N.E., Salem, Oregon. Complaint forms may be obtained by calling 378-8887.

CONSUMER RESCISSION RIGHTS

894.042. (1)(a) In addition to any other rights and remedies the purchaser may have, the purchaser of a hearing aid shall have the right to rescind the transaction if:

(A) The purchaser for whatever reason consults a licensed medical physician specializing in diseases of the ear, or an audiologist not licensed under ORS Chapter 694 and not affiliated with anyone licensed under ORS Chapter 694 and licensed medical physician, subsequent to purchasing the hearing aid, and the licensed physician advises such purchaser against purchasing or using a hearing aid and in writing specifies the medical reason for the advice, and the purchaser returns the hearing aid to the seller, or holds it at the seller's disposal, in its original condition less normal wear and tear; or

(B)(e) The seller, in dealings with the purchaser, committed any act listed in ORS 894.138, or failed to provide the statement required by ORS 894.038.

(B)(f) The purchaser of a hearing aid shall have the right to rescind provided in paragraph (a) of this subsection only if the purchaser gives written notice of the intent to rescind the transaction to the seller at the seller's place of business, by certified mail, return receipt requested, which notice shall be posted not later than 30 days following the date of delivery of the hearing aid to the purchaser.

(d) If the conditions of subparagraph (A) or (B) of paragraph (e) of this subsection and paragraph (B) of this subsection have been met, the seller, without request, refund in the purchaser within 10 days after the cancellation all deposits, including any down payment, less 15 percent of the total purchase price per 30 days as reasonable rental, and less the reasonable price of ear molds, if any, and shall return all goods traded in to the seller on account of or in contemplation of the sale less any reasonable costs actually incurred in making ready for sale goods so traded in, in which event the purchaser shall incur no additional liability for the cancellation.

(D)(e) The purchaser of a hearing aid has the right to rescind the transaction for other than the seller's breach if for reasonable cause the purchaser returns the hearing aid or holds it at the seller's dispenser's disposal and the hearing aid is in its original condition less normal wear and tear, if the purchaser sends a notice to the licensee at the licensee's regular place of business by certified mail, return receipt requested. The notice shall state that the transaction is canceled pursuant to this section, and must be mailed not later than 30 days following the date of delivery. Reasonable cause does not include a mere change of mind or cosmetic concern.

(D)(f) The licensee retains the right to a reasonable attempt to solve or eliminate problems defined within reasonable cause.

(d) If the purchaser has taken the steps described in this section to cancel the purchase and subsequently agrees with the licensee to extend the trial or rescission period, the purchaser remains entitled to receive the refund upon demand made within 60 days of the original date of delivery or such other time as agreed to in writing by both parties. Written notice of the last date for demanding a refund is to be provided to the purchaser at the time the trial or rescission period is extended.

(d) In the event of cancellation under this section, or as otherwise provided by law, the licensee must, without further request, refund to the purchaser postmarked within 10 days after such cancellation, all deposits, including downpayment, less 15 percent of the total purchase price. The licensee must also return all goods traded in on account of or in contemplation of the sale less any reasonable costs actually incurred in making ready for sale the goods.

(e) The purchaser shall incur no additional liability for a cancellation or rescission under this section.

(3) For purposes of subsection (2) of this section, reasonable cause exists in the following situations:

(a) The hearing aid or fitting and dispensing services fail to conform to any affirmation of fact or premise made by the licensee which relates to the hearing aid or fitting and dispensing services and which becomes a part of the basis of the transaction. An affirmation of fact or premise becomes part of the basis of the transaction when the purchaser relies on it or is, in part, induced into making the purchase by it;

(b) The licensee fails to advise the purchaser a description of the hearing aid or fitting and dispensing services fails to conform to the actual object or service and the licensee knows or should have known that the purchaser would use the description as part of the basis of the transaction;

(c) The hearing aid or fitting and dispensing services would fail to pass without objection in the industry under the contract description;

(d) The hearing aid or fitting and dispensing services fail to accomplish the ordinary purposes for which they are purchased;

(e) The hearing aid or fitting and dispensing services fail to satisfy an extraordinary expectation of the purchaser and, at the time the licensee performed on the contract, the licensee knew or should have known of the extraordinary expectation that the purchaser had and that the purchaser was relying on the licensee's skill and judgment to satisfy the expectation; or

(f) The licensee fails to meet any standard of conduct prescribed in the law or rules regulating the fitting and dispensing of hearing aids and this failure affects in any way the transaction which the purchaser seeks to rescind.

I have read and understood the rescission rights stated above

OCT 16 '93 15:23

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INVOICE

<input type="checkbox"/> Private Pay <input type="checkbox"/> Insurance 3600 34th Street, North Miramar Park, Florida 34665 813-827-7110 CUSTOMER NAME (LAST, FIRST)		DATE	CENTER #	DEVICE #	CUSTOMER #
			FL22	22-0198	SOCIAL SECURITY #
ADDRESS		INSURED BY			
CITY/STATE		POLICY #			
TELEPHONE #		DATE SUBMITTED			
MAKE/MODEL	EAR	STATUS	SIGNAL #	HEARING INSTRUMENT(S)	Adv. Code
MAKE/MODEL	L	STATUS	SIGNAL #	EARMOLD(S)	3045
DESCRIPTION OF PRODUCT(S) BOLO:				TESTING FEE	3100
				OTHER/CO-PAYMENT	
					4315
				SUB-TOTAL	
				INC. PAYMENT	
				TOTAL DUE	
				LESS DOWN PAYMENT	
				BAL. DUE UPON DEL.	
MINIMUM FINANCE OR CHARGE = \$18.00					
DOWN PAYMENT BY:				DATE	
<input type="checkbox"/> CASH <input type="checkbox"/> CHECK <input type="checkbox"/> MC/VISA <input type="checkbox"/> AMEX				LESS PTMT. AT DELIVERY	
DELIVERY PAY BY:				DATE	
<input type="checkbox"/> CASH <input type="checkbox"/> CHECK <input type="checkbox"/> FINANCED <input type="checkbox"/> MC/VISA <input type="checkbox"/> AMEX <input type="checkbox"/> INSURANCE				BALANCE DUE	

LIMITED WARRANTY INFORMATION

The hearing aid you have purchased is covered by a limited warranty offered by _____ for a period of _____ months.
 A separate HEARx three-year limited warranty has been included.

The terms of the limited warranty, including exclusions therefrom, are set forth on a separate form which was delivered to you prior to your purchase, in consideration of the limited warranty referred to above, except as may be set forth therein. **MAKES NO WARRANTIES OF ANY KIND, EITHER EXPRESS OR IMPLIED.**

Examinations, tests and other representations are non-medical and for the sole purpose of fitting hearing aids.

A HEARING AID WILL NOT RESTORE NORMAL HEARING, NOR WILL IT PREVENT FURTHER HEARING LOSS.

If you have any complaints regarding your hearing aid, you are encouraged to bring your complaint to this or any other Center. If your complaint cannot be resolved by _____ you are advised to contact the Department of Agriculture and Consumer Services, Division of Consumer Services, Mayo Building, Tallahassee, Florida 32399-0800, Telephone (904) 488-2221.

WAIVER

I am over the age of 18 and have been advised by HEARx that the Food and Drug Administration has determined that my best health interest would be served if I had a medical evaluation by a licensed physician (preferably one who specializes in diseases of the ear), before purchasing a hearing aid. I do not wish a medical evaluation before purchasing a hearing aid.

DISTRIBUTION OF PROSPECTIVE HEARING AID WEARER

LICENSEE NAME	LICENSEE NUMBER	CUSTOMER SIGNATURE
71014/ SC/131	DISTRIBUTION #1-PAGE #1-WHITE / Policy: #2-YELLOW / Accounting when delivered #3-PINK / Accounting when ordered: #4-GOLD / Person's Re	

★ ★ WARNING! ★ ★

1. Keep batteries out of the reach of children.
2. Batteries should be carefully discarded in receptacles that cannot be accessed by children or persons of mental incapacity.
3. Do not allow others to use your hearing aid and/or accessories as they can be misused and damage another's hearing.
4. Batteries must never be put in your mouth for any reason as they are slippery and may be swallowed accidentally.

NOTICE TO PATIENT

An itemized list of prices and services for the total purchase price of your hearing aid fitting is available upon request.

INVOICE

7101 Midlothian Tpk. Richmond, VA 23225 (804) 232-1146		<input type="checkbox"/> Private Pay <input type="checkbox"/> Insurance	DATE	CENTER #	OFFICE #	Office Hours: Monday-Friday, 9:00 a.m. - 5:00 p.m.
CUSTOMER NAME LAST, FIRST				VA23	23	CUSTOMER #
ADDRESS					SOCIAL SECURITY #	
CITY/STATE					INSURED BY	
TELEPHONE #					POLICY #	
MAKE/MODEL		EAR	STATUS	SERIAL #	HEARING INSTRUMENT(S)	Age Code X200
MAKE/MODEL		L			EARMOLD(S)	3046
DESCRIPTION OF PRODUCT(S) GOLD					TESTING FEE	3100
					OTHER/CO-PAYMENT	
						4316
					SUB-TOTAL	
					INS PAYMENT	
					TOTAL DUE	
					LESS DOWN PAYMENT	
					BAL DUE UPON DEL	
MINIMUM PAYMENT OR CHARGE — \$15.00						
DOWN PAYMENT BY		<input type="checkbox"/> CASH <input type="checkbox"/> CHECK <input type="checkbox"/> MC/VISA <input type="checkbox"/> AMEX		DATE	LESS PYMT. AT DELIVERY	
DELIVERY PAY BY		<input type="checkbox"/> CASH <input type="checkbox"/> CHECK <input type="checkbox"/> FINANCED <input type="checkbox"/> MC/VISA <input type="checkbox"/> AMEX <input type="checkbox"/> INSURANCE		DATE	BALANCE DUE	

LIMITED WARRANTY INFORMATION

The undersigned seller agrees to sell and the undersigned purchaser agrees to purchase hearing aids(s) and accessories, according to terms set forth below:

- a. The purchaser was advised that the seller is not a physician licensed to practice medicine; and
 - b. No examination or representation made by the seller should be regarded as a medical examination, opinion, or advice.
- The hearing aid you have purchased is covered by a limited warranty offered by _____ for a period of _____ months.
- I have received my separate warranty sheet. _____ Please initial

The terms of the limited warranty, including exclusions therefrom, are set forth on a separate form which was delivered to you prior to your purchase. In consideration of the limited warranty referred to above, except as may be set forth therein, I _____ MAKES NO WARRANTIES OF ANY KIND, EITHER EXPRESS OR IMPLIED.

"You, the buyer, may cancel this transaction at any time prior to midnight of the third business day after the date of this transaction. See the back of this invoice for the notice of cancellation form for an explanation of this right."

A HEARING AID WILL NOT RESTORE NORMAL HEARING, NOR WILL IT PREVENT FURTHER HEARING LOSS.

WAIVER

I am over the age of 18 and have been advised by _____ that the Food and Drug Administration has determined that my best health interest would be served if I had a medical evaluation by a licensed physician (preferably one who specializes in diseases of the ear), before purchasing a hearing aid. I do not wish a medical evaluation before purchasing a hearing aid.

SIGNATURE OF PROSPECTIVE HEARING AID WEARER

LICENSEE NAME	LICENSEE NUMBER	CUSTOMER SIGNATURE
---------------	-----------------	--------------------

71014/5/92 DISTRIBUTION #4 Part #1-WHITE / Part #2-YELLOW / Accounting when delivered #3-PINK / Accounting when ordered #4-GOLD / Private #5

OCT 19 1992 15:37

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4 * WARNINGS *

1. Keep batteries out of the reach of children.
2. Batteries should be carefully discarded in receptacles that cannot be accessed by children or persons of mental incapacity.
3. Do not allow others to use your hearing aid and/or accessories as they can be misused and damage another's hearing.
4. Batteries must never be put in your mouth for any reason as they are slippery and may be swallowed accidentally.

NOTICE TO PATIENT

An itemized list of prices and services for the total purchase price of your hearing aid fitting is available upon request.

The purchaser may return the hearing aid(s) for any reason within 30 days of the delivery date, provided the hearing aid(s) is(are) returned in satisfactory condition. The purchaser is entitled to a replacement or a refund less:

NOTICE OF CANCELLATION

You may cancel this transaction, without any penalty or obligation, within 3 business days from the above date.

If you cancel, any property traded in, any payments made by you under the contract or sale, and any negotiable instrument executed by you will be returned within 10 business days following receipt by the seller of your cancellation notice, and any security interest arising out of the transaction will be canceled.

If you cancel, you must make available to the seller at your residence, in substantially as good condition as when received, any goods delivered to you under this contract or sale; or you may, if you wish, comply with the instructions of the seller regarding the return shipment of the goods at the seller's expense and risk.

If you do make the goods available to the seller and the seller does not pick them up within 20 days of the date of your notice of cancellation, you may retain or dispose of the goods without any further obligation. If you fail to make the goods available to the seller, or if you agree to return the goods to the seller and fail to do so, then you remain liable for performance of all obligations under the contract.

To cancel this transaction, mail or deliver a signed and dated copy of this cancellation notice or any other written notice, or send a telegram, to:

[name of seller]

At _____

[address of seller's place of business]

not later than midnight of _____

(date)

I hereby cancel this transaction _____

(date)

[buyer's signature]

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REVIEW ARTICLE

MEDICAL PROGRESS

HEARING LOSS

JOSEPH B. NADOL, JR., M.D.

HEARING loss of a degree sufficient to interfere with social and job-related communication is among the most common chronic neural impairments in the U.S. population. On the basis of health-interview data,¹ it is estimated that approximately 4 percent of people under 45 years of age and 29 percent of those 65 years or over have a handicapping loss of hearing. A similar survey in Great Britain² found that approximately 25 percent of the population questioned had some hearing difficulty, and audometric evaluation of a portion of that population found that 20 percent had a hearing impairment exceeding 25 dB HL (hearing level) in the better-hearing ear. (The unit of measurement of the intensity of sound is the decibel. Changes in loudness, or sound pressure, as measured by an audiometer can be expressed mathematically as N (decibels) = $20 \log P_1/P_2$, where P_1 and P_2 are sound pressures [in dynes per square centimeter] to be compared. Thus, a 10-fold change in sound pressure will be measured as 20 dB. Clinically, loudness is expressed in decibels HL; the threshold for the perception of a sound at a given frequency by normal persons is 0 dB HL. Normal conversational levels are 45 to 60 dB, and the loudness of a jet engine at 31 m [100 ft] is 140 to 150 dB. The threshold for a handicapping hearing loss — that is, one severe enough to interfere with speech acquisition in a child or effective conversation in an adult — is approximately 25 to 30 dB.) It has been estimated that more than 28 million Americans have hearing impairment and that as many as 2 million of this group are profoundly deaf.³ The prevalence of hearing loss increases dramatically with age (Fig. 1). Approximately 1 per 1000 infants has a hearing loss sufficiently severe to prevent the unaided development of spoken language.^{4,5} More than 360 per 1000 persons over the age of 75 have a handicapping hearing loss.¹

The socioeconomic cost of hearing loss is difficult to assess. It has been estimated that the cost of only one of the many causes of hearing loss — namely, otitis media of childhood — may exceed \$3.5 billion per year in the United States.⁶ The cost of lost productiv-

ity, special education, and medical treatment may exceed \$30 billion per year for disorders of hearing, speech, and language.⁷ The most common causes of profound deafness in childhood are genetic disorders and meningitis, constituting approximately 13 percent and 9 percent of the total, respectively.⁸ In approximately 50 percent of the cases of childhood deafness, the cause is unknown. Since most of these cases may have a genetic basis,⁹ genetic causes or predisposition is probably the leading cause of hearing loss.

ANATOMY OF THE AUDITORY SYSTEM AND ANATOMICAL SITES OF HEARING LOSS

Impairments anywhere along the auditory pathway, from the external auditory canal to the central nervous system, may result in hearing loss. The auditory apparatus can be subdivided into the external and middle ear, inner ear and auditory nerve, and central auditory pathways (Fig. 2).

External and Middle Ear

Auditory stimuli are mechanically transmitted through the external auditory canal, tympanic membrane, and ossicular chain to the inner ear. The middle ear and mastoid process are normally filled with air. Disorders of the external and middle ear usually produce a conductive hearing loss by interfering with this mechanical transmission. Common causes of a conductive hearing loss include obstruction of the external auditory canal, as can be caused by aural atresia or cerumen; thickening or perforation of the tympanic membrane, as can be caused by trauma or infection; fixation or resorption of components of the ossicular chain; and obstruction of the eustachian tube, resulting in a fluid-filled middle-ear space.

Inner Ear and Central Auditory System

Auditory information in humans is transduced from a mechanical signal to a neurally conducted electrical impulse by the action of approximately 15,000 neuroepithelial cells (hair cells) and 30,000 first-order neurons (spiral-ganglion cells) in the inner ear. All central fibers of spiral-ganglion cells form synapses in the cochlear nucleus of the pontine brain stem. The auditory projections from the cochlear nucleus are bilateral, with major nuclei located in the inferior colliculus, medial geniculate body of the thalamus, and auditory cortex of the temporal lobe.¹⁰ Although the details of the neurophysiology of the inner ear and central auditory projections are beyond the scope of this review, a few specific observations are important for an understanding of the localization of hearing loss. First, the number of neurons involved in hearing increases dramatically from the cochlea to the auditory brain stem and the auditory cortex. All auditory information is transduced by only 15,000 hair cells, of which the so-called inner hair cells, numbering 3500, are critically

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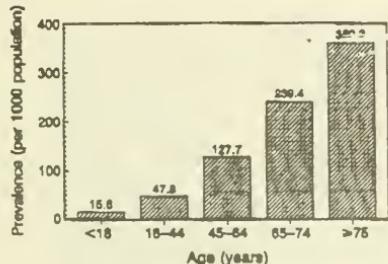


Figure 1. The Prevalence of Hearing Loss in the United States, According to Age.

These data are based on household interviews of the civilian, noninstitutionalized population. Since the data are based on self-perceived auditory handicap and not on audiometric results, they may well represent a substantial underestimate.

important, since they form synapses with approximately 90 percent of the 30,000 primary auditory neurons. By comparison, at the level of the cochlear nu-

cleus, the number of neural elements involved is measured in the hundreds of thousands. Thus, damage to a relatively few cells in the auditory periphery can lead to substantial hearing loss. Hence, most causes of sensorineural loss can be ascribed to lesions in the inner ear.

Conversely, because of the much greater number of neurons in the central auditory pathway and the bilateral ascending projections, limited lesions in the central auditory system generally do not produce an important change in the audiogram. Instead, lesions in the central auditory system tend to cause more subtle impairments, such as defective sound localization, a common finding in multiple sclerosis.

Second, the ascending auditory pathway is characterized by a tonotopic organization — that is, neural and neuroepithelial cells are grouped according to frequency specificity. For example, within the inner ear high-frequency auditory stimuli are transduced in the basal end of the cochlea and low-frequency stimuli in the apical end. Thus, damage to a portion of the inner ear will cause a specific pattern of sensorineural hearing loss. For example, aminoglycoside antibiotics preferentially damage hair cells in the basal turn of the cochlea. It is for this reason that the earliest auditory

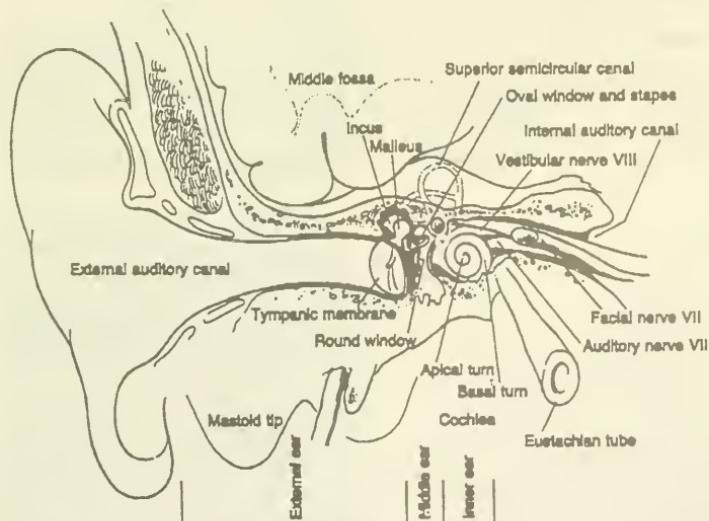


Figure 2. The Peripheral Auditory Mechanism.

The external ear consists of the external auditory canal and tympanic membrane, the middle ear consists of the air spaces of the middle ear and ossicular chain, and the inner ear consists of the cochlea, vestibular apparatus, and the eighth nerve. Acoustic stimuli are transmitted mechanically by the external and middle ear to the inner ear, where they are transduced to electrical signals for transmission to the central auditory system.

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abnormality in aminoglycoside ototoxicity is high-frequency sensorineural hearing loss (Fig. 3).

COMMON CAUSES OF HEARING LOSS

The common causes of hearing loss are listed in Table 1.

Effusions and Infections of the Ear

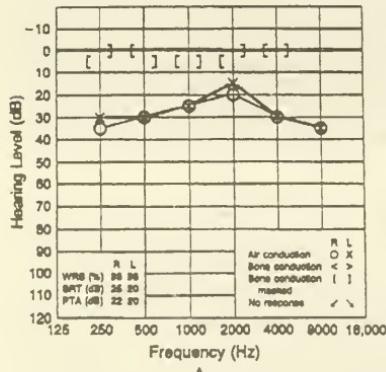
The most common cause of conductive hearing loss in childhood is otitis media with effusion, in which the middle ear and mastoid air spaces are filled with serous fluid. Malfunction of the eustachian tube, owing to mucosal disease or structural defects such as cranial-base anomalies, is a common substrate for this disorder. Acute suppurative otitis media is most common in childhood and during the winter months.¹⁹ Fortunately,

acute otitis media rarely results in more than a temporary conductive hearing loss. Despite the introduction of antibiotics, there has been little or no decrease in the incidence of chronic suppurative otitis media. Here again, a principal pathophysiologic mechanism appears to be dysfunction of the eustachian tube. Long-term negative middle-ear pressure may lead to retraction of the tympanic membrane; resorption of the ossicles; formation of cholesteatoma within the middle ear, resulting in disruption of the ossicles and the mastoid process and fibrosis of the middle ear (Fig. 4); and a handicapping conductive hearing loss. Complications of untreated chronic suppurative otitis media include sensorineural hearing loss due to suppurative labyrinthitis, brain abscess, and meningitis.

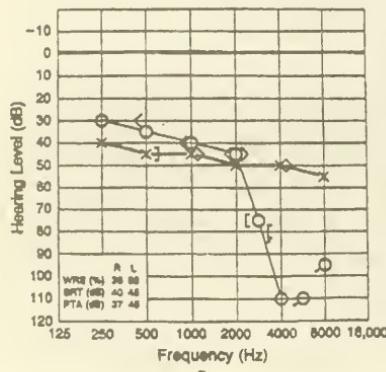
Bacterial meningitis from any cause results in sensorineural loss in 5 to 35 percent of patients who survive the disease.^{12,13} The mechanism of hearing loss appears to be suppurative labyrinthitis or neuritis (or both) resulting in the loss of hair cells or damage to the auditory nerve.²⁰

Syphilis, both congenital and acquired, can produce unilateral or bilateral sensorineural hearing loss. Syphilis can mimic a number of other disorders of hearing and balance, including Meniere's disease and immune-mediated sensorineural hearing loss. The most common clinical setting is the late latent stage; hence, the fluorescent treponemal antibody-absorption test rather than the Venereal Disease Research Laboratory flocculation test or the rapid plasma reagins test may be necessary to make the diagnosis. Treatment with antibiotics and corticosteroids may stabilize or improve hearing.²¹

Tuberculosis of the temporal bone²² can cause multiple perforations of the tympanic membrane, chronic



A



B

Figure 3. Results of Behavioral Audiology.

Audiometry was used to determine the behavioral threshold for pure tones from 250 to 4000 Hz for bone conduction, in which an acoustic stimulus was delivered through a bone oscillator to the skull (thereby bypassing the external and middle ear), and from 250 to 8000 Hz for air conduction, in which an acoustic stimulus was delivered through headphones (thereby engaging all normal mechanisms of sound transmission). In addition, the word-reception score (WRS) was used as a measure of speech discrimination; the score is based on the percentage of phonetically balanced words correctly repeated by a subject when heard at approximately 40 dB above measured threshold. In general, speech-discrimination scores tend to be normal in patients with a conductive hearing loss and low in patients with retrocochlear (neural) lesions. Panel A shows the results for a patient with a bilateral conductive hearing loss of approximately 30 dB, consistent with the presence of a serous effusion or ossicular fixation. Panel B shows the results for a patient with an asymmetric sensorineural hearing loss that is worse in the right ear. The reduced WRS (30 percent) in the right ear is suggestive of a retrocochlear lesion. BRT denotes speech-reception threshold; PTA, pure-tone average of thresholds at 500, 1000, and 2000 Hz; R, right ear; and L, left ear. The presentation of narrow-band noise to the non-test ear is called masking; it is indicated whenever there is the possibility that the measured threshold of hearing may actually reflect hearing in the non-test ear.

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Table 1. Common Causes of Hearing Loss.

DISORDER	TYPE OF HEARING LOSS	APPROXIMATE INCIDENCE OR PREVALENCE OF KNOWN	REFERENCE
Effusions and infections			
Otitis media with effusion	Conductive	80% of children between 0–6 yr of age	Sant and Field ⁴
Chronic otitis media	Conductive, sensorineural	18/100,000 population/yr	Rabins ¹¹
Syphilis (congenital and acquired)	Sensorineural	—	
Tuberculosis	Conductive, sensorineural	—	
Bacterial meningitis	Sensorineural	Approximately 25% of patients	Krasny et al. ¹² Nadol ¹³
Viral infection, maternal rubella, cytomegalovirus disease, other?	Sensorineural	—	
Genetic and developmental disorders			
Wiedemann's syndrome	Sensorineural	Approximately 1–2% of patients with congenital deafness	Kouyoumdjian ¹⁴
Usher's syndrome	Sensorineural	Approximately 3–10% of patients with congenital deafness	Praus ¹⁵
Ajzenberg's syndrome	Sensorineural	Approximately 1% of all patients with genetic deafness	Kouyoumdjian and Gorlin ¹⁶
Osteopetrosis	Conductive, sensorineural	Approximately 3–8/1000 white	Kouyoumdjian and Gorlin ¹⁶
Autosomal dominant or recessive sensorineural deafness	Sensorineural	—	
Drug-induced deafness			
Aminoglycosides	Sensorineural	—	
Loop diuretics	Sensorineural	—	
Cephalosporins	Sensorineural	—	
Salicylates	Sensorineural	—	
TRAUMA			
Falls, falls from height	Conductive, sensorineural	—	
Penetrating injury of ear	Conductive, sensorineural	—	
Acoustic trauma (exposure to noise)	Sensorineural	—	
Radiation-induced injury	Sensorineural	—	
Intrinsic-mediated diseases			
Weber's granulomatosis	Conductive, sensorineural	—	
Giant-cell arteritis	Sensorineural	—	
Lupus erythematosus	Sensorineural	—	
Polymyositis nodosa	Sensorineural	—	
Primary neoplastic processes			
Acoustic neuroma	Sensorineural	1.5–850/100,000 population	Stewart et al. ¹⁷
Squamous-cell carcinoma	Conductive, sensorineural	—	
Chemotherapies	Conductive, sensorineural	—	
Metastatic lesions	Sensorineural	—	
Carcinoma of breast, prostate, or kidney	Sensorineural	—	
Mitophagic and degenerative disorders			
Prader-Willi syndrome	Sensorineural	30% of U.S. population over 70 yr of age	Public Health Service ¹⁸
Meckel's disease	Sensorineural	10–180/100,000 population	Phelan and Theodore ¹⁹
Sudden idiopathic sensorineural loss	Sensorineural	—	
Cervical disorders	Sensorineural	—	
Vestibular insufficiency	Sensorineural	—	
Ketotifen	Sensorineural	—	
Hyporesponsiveness tests	Sensorineural	—	

granulomatous otitis media, a cervical abscess medial to the sternocleidomastoid muscle (Bezoard's abscess), and both conductive and sensorineural hearing loss. It is rare in the absence of primary pulmonary tuberculosis. Tuberculous otitis media may mimic chronic otitis media and, hence, may be seen clinically as persistent disease after mastoid surgery.

The role of viruses in the production of sensorineural loss is controversial. The evidence of viral-induced sensorineural loss is strongest for maternal rubella,²⁰ cytomegalovirus,²¹ and herpes zoster.²² Although mea-

sles, mumps, and other common viruses are often cited as causative agents, their role in postnatal hearing loss remains unproved.²³ Sensorineural hearing loss may also occur in patients with the acquired immunodeficiency syndrome as a result of opportunistic infections of the temporal bone or cerebellopontile angle.²⁷

Genetic and Developmental Disorders

The true incidence of genetic causes of conductive and sensorineural hearing loss is unknown. It has been estimated that at least 50 percent of cases of pro-

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found deafness in childhood have genetic causes.²⁸ If one takes into consideration the probability that genetic predisposition is a major causative factor in presbycusis, which affects one third of the population over 75 years of age,²⁹ genetic and hereditary factors are probably the single most common cause of hearing loss. Konigsmark has written an excellent review of hereditary deafness in humans.¹⁴ In congenital or early-onset genetically determined deafness, the pattern of inheritance is autosomal recessive in 60 to 70 percent of cases, autosomal dominant in 20 to 30 percent, and X-linked in 2 percent.³⁰ Genetic-linkage analysis has been accomplished in Usher's syndrome³¹ (retinitis pigmentosa and congenital sensorineural deafness) and Waardenburg's syndrome (sensorineural deafness, laterally displaced medial canthi, broad nasal root, white forelock, and heterochromia iridis).³² Genetic lesions may cause both conductive and sensorineural hearing loss as part of recognizable syndromes or with no associated abnormalities.

At least 50 hereditary syndromes produce conductive hearing loss, usually mediated by dysplasia or fixation of the ossicles of the middle ear or by malformation of the external auditory canal.³³ The most common genetically transmitted disorder producing conductive hearing loss is otosclerosis. Approximately 1 percent of the population is affected, usually in both ears. Up to 10 times that number may have histologic involvement of the temporal bone in a form that is not clinically apparent.³⁴ Conductive hearing loss is caused by fixation of the stapes footplate (Fig. 5), and involvement of the endosteum of the inner ear may cause a concomitant sensorineural hearing loss.³⁵ Although clearly demonstrating a pattern consistent

with autosomal dominant inheritance, chronic osteitis due to measles virus has been suggested as a cofactor in the pathogenesis of conductive hearing loss.³⁶ Less common genetic causes of conductive hearing loss include osteogenesis imperfecta³⁷ and the Klippel-Feil syndrome (sensorineural deafness and fusion of cervical vertebrae).³⁸

Genetic anomalies are much more commonly expressed as sensorineural hearing loss than as conductive hearing loss. The actual incidence of genetically determined sensorineural hearing loss is unknown, but it is clearly a major, if not the main, cause of sensorineural loss, particularly in children.³⁹ The majority of cases of genetically determined sensorineural loss probably occur in an autosomal recessive form and not as part of a clinical syndrome, as reviewed by Konigsmark.¹⁴ Nonsyndromal sensorineural hearing loss that is genetically determined may be congenital or late in onset, progressive or nonprogressive. The most common audiometric pattern is mid- or high-frequency loss; however, a low-frequency predominance has also been described.³⁹ Although genetically determined sensorineural hearing loss is usually bilateral, asymmetric or even unilateral⁴⁰ hearing loss has been described. In addition, genetically determined sensorineural loss has been described in conjunction with abnormalities of the external ear, skin, eye, central nervous system, musculoskeletal system, kidneys, and other organs. Among the most common syndromal forms of sensorineural loss are Waardenburg's syndrome, Alport's syndrome (sensorineural deafness and nephritis), and Usher's syndrome.

In addition to genetically determined causes, congenital hearing loss may be seen in a variety of conditions, including those caused by intrauterine exposure to thalidomide,⁴¹ quinine intoxication,⁴² hypothyroidism,⁴³ maternal rubella,⁴⁴ the CHARGE association⁴⁵ (coloboma, heart disease, atresia of the nasal choanae, retarded development, genital hypoplasia, and ear anomalies), prematurity,⁴⁶ neonatal jaundice,⁴⁷ cerebral palsy,⁴⁸ and intrauterine exposure to tretinoin.⁴⁹

Ototoxicity

A variety of commonly used drugs have ototoxic properties. The best known are the aminoglycoside antibiotics,^{50,51} loop diuretics,⁵² salicylates,⁵³ and antineoplastic agents such as cisplatin.⁵⁴ In addition, ototoxicity has been described during oral or parenteral administration of erythromycin.^{55,56} Increased toxicity in the presence of renal failure is a well-known characteristic of some drugs, particularly aminoglycosides, and a synergis-

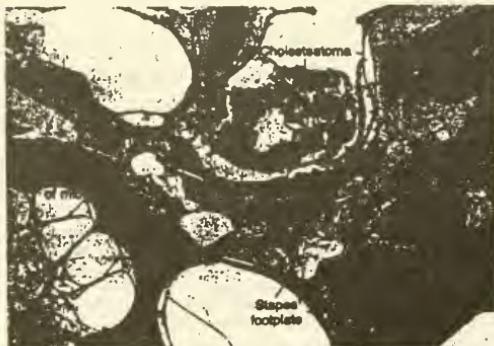


Figure 4. Chronic Otitis Media of the Right Ear in a 64-Year-Old Man (Hematoxylin and Eosin, $\times 3$). A cholesteatoma is present within a retraction pocket that extends from the tympanic membrane into the middle-ear space.

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Figure 5. Otosclerosis in an 81-Year-Old Man Causing Fixation of the Stapes Footplate (Hematoxylin and Eosin, $\times 12.8$). The endosteum of the cochlea is involved.

tic effect of other ototoxic substances, such as loop diuretics,³⁷ has been described. Most ototoxic substances cause hearing loss by damaging the cochlea, particularly the auditory hair cells and stria vascularis, a specialized epithelial organ within the inner ear responsible for the homeostasis of fluids and electrolytes. Ototoxicity can be prevented by careful monitoring of patients, particularly those with compromised renal function or those receiving more than one ototoxic drug. In addition to measurements of peak and trough serum levels, pretreatment audiometry and vestibular testing, followed by weekly tests during treatment, are useful in high-risk patients. Daily questioning of the patient for the presence of tinnitus or vestibular symptoms is advisable, although one must keep in mind that a bedridden patient may not have nystagmus or vestibular symptoms despite the onset of toxic vestibulopathy. Furthermore, although bilateral auditory involvement is the rule, an asymmetric effect is common. Secondary neural degeneration may occur many years after an ototoxic event. There is evidence that some ototoxic substances may be selectively concentrated within the inner ear, resulting in progressive sensorineural loss despite the discontinuation of systemic administration.³⁸

Trauma

Closed or penetrating injuries of the skull and temporal bone can result in conductive or sensorineural hearing loss or both. Longitudinal fractures through the temporal bone generally result in perforation of the tympanic membrane, disruption of the external auditory canal and ossicular chain, bloody otorrhea, and conductive hearing loss. Sensorineural hearing loss is less common. Fractures transverse to the long axis of the temporal bone can result in a hemato-

tympanum and are much more likely to cause permanent and profound sensorineural loss by disrupting the cochlea or auditory nerve. Concussive injuries of the skull without fracture may result in high-frequency sensorineural hearing loss similar to that seen in acoustic trauma.

There is individual susceptibility to trauma from noise. Clinically important sensorineural hearing loss may occur in some people exposed to high-intensity noise even below levels approved by the Occupational Safety and Health Administration.³⁹ In addition to individual susceptibility, there may be synergy with commonly self-administered medications such as aspirin. Serial audiometry is the only way to be certain of the possible deleterious effects of noise in a given patient. However, a useful clinical guideline

is that if a noise is sufficiently loud to be painful or to cause tinnitus or a temporary sensation of blocking in the ears, it is likely that prolonged exposure to the noise will cause permanent sensorineural loss.⁴⁰

Barotrauma usually occurs during descent from high altitude in which there is a rapid increase in air-craft pressure in the presence of compromised function of the eustachian tubes owing to upper respiratory tract infection or allergy. The inability to equalize air pressure on the external-canal and middle-ear sides of the tympanic membrane leads to substantial negative pressure within the middle ear, resulting in serous or bloody effusion and then pain and temporary conductive hearing loss but rarely permanent damage to the inner ear.

Rupture of the membranous barrier between the middle ear and inner ear at the oval or round windows may result in leakage of fluid from the inner ear. Such a "perilymphatic fistula" may cause progressive or fluctuating sensorineural loss and vestibular symptoms. A fistula usually forms after head trauma, heavy lifting, or straining, or occasionally during barotrauma. Unfortunately, there is currently no diagnostic option available other than surgical exploration of the middle ear to confirm this diagnosis. Repair of a fistula with a tissue graft may stabilize the hearing loss and eliminate the vestibular symptoms.⁴¹

Lumbar puncture with or without the introduction of a radiographic contrast agent may result in hearing loss, presumably due to the rapid decrease in spinal fluid and perilymphatic pressure.⁴²

Irradiation of the head and neck region directed at lesions within the temporal bone or adjacent areas such as the nasopharynx may result in a conductive hearing loss due to osteoradionecrosis⁴³ or a

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sensorineural hearing loss presumably due to radiation labyrinthitis.¹⁴

Immune-Mediated Sensorineural Hearing Loss

Several systemic immune-mediated disorders, including Cogan's syndrome¹⁵ (nonsyphilitic interstitial keratitis with vestibuloauditory symptoms), relapsing polychondritis,¹⁶ polyarteritis nodosa,¹⁷ Wegener's granulomatosis,¹⁸ lupus erythematosus,¹⁹ Behcet's disease,²⁰ and giant-cell arteritis,²¹ are known to cause hearing loss. Histopathological study of the temporal bones in patients with these disorders supports the view that vasculitis and an inflammatory infiltrate are the cause of sensorineural hearing loss (Fig. 6).

More recently, a form of immune-mediated sensorineural hearing loss without other systemic manifestations has been recognized.²² The hearing loss is usually bilateral, is rapidly progressive (measured in weeks or months), and may or may not be associated with vestibular symptoms. The diagnosis of this form is difficult. Currently, immunoassay (by Western blotting) for circulating antibodies to inner-ear protein holds the most promise as a diagnostic tool.^{23,24}

Demyelinating processes, such as multiple sclerosis, may cause sensorineural hearing loss.²⁵ The first signs of auditory dysfunction may be subtle, such as impairment of sound localization or latency changes in auditory evoked brain-stem responses, both of which reflect prolonged conduction velocities in central auditory pathways.

Tumors

A variety of tumors, both primary and metastatic, can produce either a conductive hearing loss, by interfering with the motion mechanics of the middle ear and ossicles, or a sensorineural hearing loss, by invading the inner ear or auditory nerve. Rarely, hearing loss may be due to meningeal carcinomatosis involving the auditory nerve within the internal auditory canal.²⁶ The most common primary tumors arising within the temporal bone are acoustic neuroma, chondroblastoma, squamous-cell carcinoma, adenocarcinoma, and basal-cell carcinoma. The most common metastatic lesions to the temporal bone are adenocarcinoma of the breast in women and prostatic and renal-cell carcinoma in men.

Idiopathic and Degenerative Disorders

A variety of degenerative disorders of unknown cause can produce sensorineural hearing loss. Meniere's syndrome,²⁷ characterized by fluctuating sensorineural hearing loss, episodic vertigo, and tinnitus, appears to be caused by a disorder of fluid homeostasis within the inner ear, although the pathogenesis remains unknown. Sudden idiopathic sensorineural hearing loss,²⁸ causing moderate-to-severe sensorineural deafness, may be due to viral labyrinthitis.

Presbycusis, the hearing loss associated with aging, is by no means universal, but it affects more than one third of persons over the age of 75 years. The most

common histopathological correlate of presbycusis is the loss of neuroepithelial hair cells, neurons, and the stria vascularis of the peripheral auditory system.²⁹ Although less well understood, degenerative processes probably also occur in the central auditory pathway.^{30,31} Presbycusis is best understood as resulting from the cumulative effects of several noxious influences during life, including noise trauma, ototoxicity, and genetically influenced degeneration.

Disorders of the Circulation

The vascular supply of the inner ear can be compromised by hemorrhage into the internal auditory canal and inner ear, interference with the vertebral-basilar circulation, embolic phenomena, and hypercoagulable states. Spontaneous hemorrhage into the inner ear has been described as a complication of leukemia,³² Wegener's granulomatosis, trauma to the temporal bone, and subarachnoid hemorrhage. The vascular supply to the inner ear is provided by the anterior or inferior cerebellar artery, a branch of the vertebral-basilar system. Occlusion of this vessel will result in profound sensorineural hearing loss and usually in vertigo. More proximal occlusion may result in Wallenberg's syndrome.³³ In this syndrome, hearing loss is a variable symptom. Hearing loss has also been reported in basilar migraine.³⁴ Sudden hearing loss has been described as a complication of fat emboli and the hypercoagulable state.^{35,36}

DIAGNOSTIC APPROACHES

Given the many possible causes of hearing loss, a thorough history is essential for diagnosis. The nature of the onset of the hearing loss — unilateral, bilateral, fluctuating, progressive, sudden, or insidious — is an important differential symptom. The presence of other concurrent aural symptoms, such as pain and discharge; vertigo; facial-nerve symptoms; and other nonaural symptoms, including other cranial-nerve or generalized neurologic disturbances, will likewise help direct the subsequent evaluation. It is also useful to know whether there were predisposing factors, such as trauma, exposure to noise, use of medications, intercurrent disease including neoplastic processes, and a family history of hearing loss.

The physical examination should include not only visualization of the tympanic membrane and clinical tests of hearing, such as the tuning-fork and whisper tests, but also a complete head and neck and cranial-nerve examination and, if indicated, a neurologic examination.

The mainstay of ancillary testing remains behavioral (pure-tone and speech) audiometry. Measurement of the auditory evoked brain-stem response is useful in very young or uncooperative patients. In this test, neural responses to auditory stimuli can be detected during electroencephalography by signal-averaging techniques (Fig. 7). By varying the intensity of the acoustic stimuli, a threshold approximating the behavioral threshold can be determined. In addition, at



Figure 6. Polyarteritis Nodosa Involving the Left Inner Ear of a 66-Year-Old Woman. The patient noted a hearing loss on the left side approximately seven months before her death. There is severe degeneration of the inner ear, including the spiral ganglion (Panel A) (hematoxylin and eosin, $\times 7.8$). The lumen of the labyrinthine artery, seen at a higher magnification in Panel B (hematoxylin and eosin, $\times 290$), is almost completely obliterated as a result of thickening of the adventitia, media, and intima. Reprinted from Schuknecht¹⁷ with the permission of the publisher.

suprathreshold levels, prolongation of the interwave time latencies of the auditory evoked brain-stem response provides a sensitive indicator of retrocochlear (auditory nerve or brain stem) lesions.¹⁰ Vestibular testing in the form of electronystagmometry, rotational tests, and posturography are useful adjuncts when there are concomitant vestibular symptoms.

Modern imaging techniques have revolutionized neuro-otologic diagnosis. Computed tomography is particularly useful for identifying bony lesions of the temporal bone and mastoid process, and magnetic res-

onance imaging, particularly with gadolinium enhancement, is now capable of demonstrating lesions such as acoustic neuromas measuring 5 mm in diameter in the internal auditory canal. Given that hearing loss due to a systemic disease that does not have other clear clinical manifestations is unlikely, serologic and chemical screening should be based on the history and physical findings. Exceptions include the use of the fluorescent treponemal antibody-absorption test¹¹ for late latent syphilis, in which hearing loss may be the only symptom, and immunoassay (Western blotting) for suspected immune-mediated sensorineural hearing loss in the absence of systemic manifestations.¹²

TREATMENT

Although the details of treatment strategies for hearing loss are beyond the scope of this review, a few comments about what is clinically available for patients with hearing loss are warranted.

Treatment and Rehabilitation of Conductive Hearing Loss

Most patients with congenital and acquired causes of conductive hearing loss can be helped by modern tympanoplasty (repair of the tympanic membrane), ossiculoplasty (reconstruction of the ossicular chain), and stapedectomy (replacement of an ankylosed stapes with a prosthesis).^{13,14} Most recently, further improvements in surgical results have been achieved by refinement of techniques, such as intraoperative electrophysiologic monitoring of the facial nerve and the use of laser techniques in middle-ear surgery. The introduction of bioactive alloplastic materials, such as hydroxyapatite, has improved the stability of ossicular reconstructions of the middle ear. In addition, hearing aids are a useful nonsurgical option for most patients with conductive hearing loss.

Treatment and Rehabilitation of Sensorineural Hearing Loss

The evaluation of sensorineural loss should include a strategy to identify an increasing number of causes that are amenable to medical or surgical treatment, such as syphilis in the latent or congenital form, im-

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Oct. 7, 1993

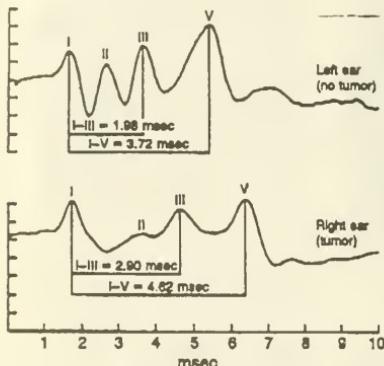


Figure 7. Auditory Evoked Brain-Stem Responses in the Left and Right Ears of a 27-Year-Old Patient with a Normal Pure-Tone Audiogram and Reduced Speech Discrimination (84 Percent) in the Right Ear.

The I through III and I through V interwave latencies were markedly prolonged in the right ear, consistent with a diagnosis of a retrocochlear lesion. A cavernous hemangioma measuring 1 cm in diameter was confirmed by magnetic resonance imaging and subsequent surgery. Each division of the vertical axis represents 200 nV.

mune-mediated sensorineural hearing loss, acoustic neuroma, sudden idiopathic sensorineural hearing loss, and perilymphatic fistula. For example, left untreated, late latent syphilis will often cause profound bilateral sensorineural hearing loss, whereas treatment with a combination of corticosteroids and antibiotics may stabilize or even improve hearing.²¹

The approach to the management of immune-mediat-

ed sensorineural loss has undergone rapid evolution. Current treatment includes long-term therapy with corticosteroids or, in some cases, immunosuppression or plasmapheresis.^{25,27}

The management of acoustic neuroma has improved dramatically in the past 15 years. For most lesions preservation of the facial nerve and, in some cases, of hearing can be expected after surgical resection.²⁸

The ability to treat idiopathic sudden sensorineural hearing loss suffers from a lack of a known cause. However, it is clear that prompt treatment with corticosteroids is beneficial in a subgroup of patients.²¹

Perilymphatic fistula, although uncommon, is amenable to surgical repair with free-tissue grafts to the oval or round windows.

Early identification of meningitis²⁹ and the use of corticosteroids in the therapeutic regimen for childhood meningitis³⁰ may reduce the incidence of sensorineural hearing loss as a sequela of this disorder.

Hearing aids are still the mainstay of the treatment of patients with sensorineural hearing loss that is not amenable to medical or surgical management. The modern hearing aid has improved greatly. Programmatic hearing aids and amplification circuits that reduce distortion are generally available. Modern circuitry has resulted in more dependable and smaller aids. Some fit entirely within the external auditory canal. Totally implantable aids may become available within the next 10 years. Cochlear implants, which provide a neural prosthesis for the rehabilitation of profound sensorineural deafness (Fig. 8), have proved valuable to patients with profound deafness, for whom a conventional hearing aid is not feasible.³¹

The enactment of the Americans with Disabilities Act in 1990 should result in improved access for the hearing impaired to sound and signaling devices in public places. A variety of classes and self-help groups provide training in such techniques as cued speech,

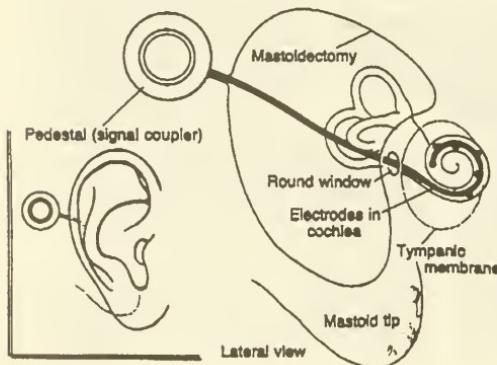


Figure 8. Cochlear Implant.

The implant consists of an electrode array inserted into the inner ear by a mastoidectomy through the round window. An externally worn signal processor interfaces with the cochlear implant at the signal coupler.

auditory training, speech reading, and manual methods such as American Sign Language. These groups, including Self-Help for Hard of Hearing People, the Association of Late-Deafened Adults, and the American Speech Language Hearing Association, offer rehabilitative services for the hearing impaired. Improved understanding of the pathogenesis of hearing loss, particularly through information obtained by genetic-linkage analysis, holds the promise of the prevention of some forms of this formidable handicap in the future.

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14 October 1993

The Honorable David Pryor
Chairman
Special Committee on Aging
United States Senate
G31 Dirksen Senate Office Building
Washington, DC 20510-6400

Dear Senator Pryor:

Thank you for the opportunity to submit written testimony to the Special Committee on Aging in response to your Sept. 15 hearing on the hearing aid industry.

Miracle-Ear supports a number of principles presented by members of the committee. Those principles include quality, affordability, competency and access. And from that common ground, we believe that together we can build trust in the industry and bolster the quality of hearing health care in America.

Our goal is that consumers be assured that hearing aid specialists will provide good quality health care in a disciplined health care environment.

The hearing that you conducted with Sen. Cohen was fair and impartial. Members of the committee have repeatedly solicited the industry's thoughts to resolve the issues you have identified. We trust our testimony will re-affirm our desire to be both a part of the discussion -- and the solution.

Again, thank you. We look forward to the opportunity of further discussions with you.

Sincerely,

A handwritten signature in black ink, appearing to read "Ben Wofford".

W. Ben Wofford

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Testimony by

**W. Ben Wofford
President
Miracle-Ear®
Golden Valley, Minn.**

For more than 45 years, Miracle-Ear has been helping millions of Americans hear better. Our company prides itself in manufacturing the finest hearing instruments and providing some of the best customer service in the industry through 1,000 conveniently located Miracle-Ear hearing centers. And the hundreds of letters we get each year from satisfied customers confirm that reality.

Over this past year, however, we have encountered a different reality – negative public perception of the industry and of Miracle-Ear. And perception is reality. It's reality when customers cancel their appointments following the *Dateline NBC* broadcast. It's reality when the FDA issues warning letters to hearing aid manufacturers. It's reality when the Senate spends many months investigating the industry – and finds issues of great concern.

Something is wrong. And we want to fix it. Miracle-Ear – and the industry – must move swiftly on all fronts to build the trust and respect of consumers, advocacy groups, the media, state and local regulators, and Congress.

Miracle-Ear wishes to work cooperatively with committee members and the Administration to assure quality hearing health care in a disciplined environment. It's obvious that the Clinton Administration and Congress have a sincere interest in hearing health care. Miracle-Ear seeks a collaborative and cooperative approach to resolving issues of hearing health care.

Miracle-Ear concurs with a number of principles presented by Democratic and Republican members of the Select Committee on Aging. Those principles include:

- Quality
- Affordability
- Competency and
- Access.

And from that common ground, we believe that together we can bolster the quality of hearing health care in America. Our goal is that consumers be assured that hearing aid specialists will provide good quality health care in a disciplined health care environment.

Quality.

Miracle-Ear designs have been engineered to best meet the unique hearing needs of individuals. Our hearing instruments have undergone rigorous testing and are manufactured by highly skilled technicians in the finest facilities in the world. We stand by our hearing instruments in four ways:

- A minimum 30-day trial period during which a consumer can get acquainted with a Miracle-Ear hearing instrument and all adjustments are made at no additional charge;
- A 2-year warranty provided to franchisees which covers all parts and workmanship,
- A 2-year loss and damage protection plan.
- An information package which accompanies a new hearing aid that includes all FDA-required materials and directions, wearing schedule and rehabilitation instructions, reminders for follow-up evaluations, as well as cleaning and maintenance tools and supplies.

Hearing aids are a medical device and as such, manufacturers should support any performance claims – beyond the general claim of improved hearing – with clinical data. But the clinical data cannot be comparable to that collected for other medical devices under the FDA's 510 (k) review process. Rather, it must be collected in a regimen which takes into account the uniqueness of a person's hearing health and the living situations each person encounters.

Miracle-Ear wishes to work closely with the FDA's Center for Devices and Radiological Health to devise those guidelines and has communicated that desire to the FDA.

Miracle-Ear has moved aggressively to ensure that all of our customers are satisfied with the performance of its products and the services provided by our franchisees and their employees.

Our policy is simple: If you are not satisfied with your Miracle-Ear hearing instrument or the service of the franchisee from which you obtained the instrument, Miracle-Ear headquarters will refund your money, less a fitting fee. No hassles. No delays.

To put teeth in our satisfaction policy, we maintain a customer complaint index on every franchisee and monitor it closely to be sure they are adhering to the policy, as well as following all state and federal regulations. Every customer complaint that is made to Miracle-Ear headquarters is followed up with the consumer and franchisee until it is resolved to the customer's satisfaction.

We track the franchisee's efforts to resolve the complaint and are quick to step in and resolve it ourselves to the satisfaction of the customer. Any franchisee or franchise employee with a pattern of complaints will be dealt with harshly.

The West Virginia case cited in your investigation was particularly troublesome and spurred continuous improvements in our franchise monitoring. Miracle-Ear headquarters was not informed of the four-year investigation and consent order by the state attorney general's office until notified by a consumer in August 1992. We immediately contacted the West Virginia attorney general's office and offered our assistance.

Two weeks later, the franchisee was notified he was in default of his contract with Miracle-Ear and would be terminated in 30 days, as identified in his contract, if he could not "cure" the complaints identified by the state and Miracle-Ear. The franchisee failed to fulfill his obligations and was terminated in early October 1992.

Miracle-Ear also identified consumers with complaints against the former franchisee and we voluntarily resolved each one by repairing or replacing hearing instruments or providing refunds.

Unfortunately, six years after the consent order and judgment, the terminated franchisee continues to dispense other brands of hearing aids. State licensing boards must have greater power to pull licenses in an expeditious manner.

Affordability.

Miracle-Ear hearing aids are highly sophisticated medical devices which are priced competitively with those of other quality manufacturers. Our Miracle-Ear hearing centers include the cost of fitting, instruction, follow-up care and counseling in the price of each hearing aid. Testing is a complimentary service.

Unfortunately, for some consumers, the cost remains prohibitive. Hearing aid costs are not reimbursable under the current Medicare system, nor are they covered in the Administration's health care reform proposal.

Members of the committee pointedly noted that whatever changes are made in the industry, the cost of hearing health care cannot increase. Costs have remained fairly stable over the years because of access to an extensive array of hearing health providers, particularly hearing instrument specialists. Should access to hearing health care be restricted to audiologists and physician specialists, costs will increase. This cannot be permitted.

National Minimum Competency Standards.

Some 5,300 hearing aid specialists are on the front lines of hearing health care in America. If their role were to be eliminated, it would cut the nation's hearing aid dispensers by more than half. This would have a devastating impact in rural communities and small towns where other more costly hearing health care providers are located many miles away.

And it would magnify the lack of hearing health care experience exhibited by many general practitioners. Dr. Kessler noted in his testimony to the committee that the bulk of general-practice physicians have less knowledge about hearing impairment, appropriate testing procedures and hearing instruments than audiologists or hearing aid specialists.

The Administration should encourage the use of lower-cost, accessible and qualified allied health professionals such as hearing aid specialists. But it should unify the myriad of competency standards required for licensing from one state to the next.

Miracle-Ear conducts its own program in competency accreditation, continuing education and certification through National Board Certification of Hearing Instrument Sciences. Nonetheless, Miracle-Ear is supportive of the committee and Commissioner Kessler in its efforts to adopt national minimum competency standards for all hearing health care providers.

Congress and the FDA may want to look to a number of states whose laws could be used as models for the national minimum standards for hearing aid specialists. Recently approved regulations in Texas are a good example. They require, among other rigorous qualifications, performance-based demonstrations of hearing health competence.

Here are some key points from the Texas law which may help shape a national competency standard:

A temporary licensee in Texas must complete 200 days of training, including 150 hours of direct supervised practicum in specific areas of hearing health, evaluation and technology.

A temporary license holder must then obtain an apprentice license by passing a written and practical exam before the licensing board.

To become a licensed hearing instrument specialist, an apprentice hearing aid specialist must work for one year under the supervision of a licensed hearing instrument specialist and attend 18 hours of continuing education classes.

Existing license holders must attend 20 hours of continuing education courses each year, 5 hours of which can be conducted by a manufacturer, the balance by other professionals approved by the licensing board.

If the Texas law were to be applied nationally, many current and prospective hearing aid specialists in other states may have to attend additional classes and pass more stringent tests than currently mandated in those states. We feel the time and effort would be more than worth it. By enacting national minimum standards of this type, we can enhance the confidence we want our customers to have in Miracle-Ear products and services.

But these standards and other requirements particular to each state are of no value if they are not enforced.

Miracle-Ear also supports the development of a standard hearing health evaluation, along with a uniform patient history questionnaire to be used by all hearing health care providers. Both would go a long way in ensuring quality hearing health care.

Miracle-Ear is eager to work with the Center for Devices and Radiological Health to develop each of these testing protocols.

Miracle-Ear also supports mandatory referrals to a physician specialist when a hearing exam or medical history indicates the presence of any of eight specific conditions. At Miracle-Ear, we have always instructed mandatory medical referrals in these cases, even though FDA regulations do not require it. We support the creation and dissemination of additional literature that would ensure that every consumer is fully informed and understands it is in his/her best health interest to have a medical examination prior to the first-time purchase of a hearing aid.

Access and the Vermont Exemption.

We support the committee's endeavor to maintain the access consumers currently have available through community-based hearing health care services.

Licensed hearing aid specialists and audiologists can act as qualified and affordable gate-keepers in hearing health care. They can test hearing-impaired persons at a low cost, fit the right hearing instrument for a person's unique needs, and, if necessary, refer them to a physician should the hearing test or medical history indicate the potential for a medical condition.

We support Dr. Kessler's desire to approve the Vermont waiver along with his provision that such hearing health professionals as hearing aid specialists, audiologists and otolaryngologists can conduct the mandated hearing tests - as long as they have met certain competency standards and passed the required tests.

But those standards cannot be so onerous that they restrict access of Vermont's residents to quality hearing health care. That is particularly critical to residents of such Vermont communities as St. Albans where the nearest physician, specialist or audiologist is 30 miles away.

A hearing aid specialist who operates in communities like St. Albans can conduct a hearing test to determine if a hearing aid would be necessary, or in a minority of cases, if referral to a physician should be made.

Conclusion.

Mr. Chairman and members of the committee, Miracle-Ear/Bausch & Lomb is grateful for the opportunity to submit for the record our suggestions to help us re-instill confidence in the hearing health industry.

The hearing you conducted was fair and impartial. Members of the committee have repeatedly solicited the industry's thoughts to resolve the issues you have identified. We trust our testimony will re-affirm our desire to be both a part of the discussion - and the solution: To assure consumers that hearing aid specialists will provide good quality health care in a disciplined health care environment.

APPENDIX 3



OFFICE OF
THE CHAIRMAN

UNITED STATES OF AMERICA
FEDERAL TRADE COMMISSION
WASHINGTON, D.C. 20580

October 18, 1993

The Honorable David Pryor
Chairman
Special Committee on Aging
United States Senate
Washington, D.C. 20510-0402

Dear Mr. Chairman:

Thank you for your letter of September 10, 1993, inviting the Federal Trade Commission to submit a written statement for the record on issues relating to the advertising and marketing of hearing aids, the subject of a hearing conducted by the Committee on September 15. The Commission is pleased to provide the Committee with a summary of the agency's activities to address problems in the hearing aid industry, including law enforcement efforts, consumer education, and liaison with the states.

Hearing loss affects 24 million Americans, most of whom are elderly. In fact, some 62 percent of hearing aid purchasers are over 65 years of age. Of these 24 million potential users, approximately 5.8 million wear some form of hearing instrument.¹ In 1991, approximately 1.42 million hearing aids were sold, at an average retail price of \$667.00.²

The Commission shares the Committee's concern about the substantial consumer injury that can result from deceptive practices in the advertising and marketing of hearing aids. The Commission is one of several agencies actively addressing these problems. Hearing aid dispensers are licensed and regulated at the state and local level, and state and local law enforcement agencies traditionally have taken the initiative in combatting abuses occurring at the point-of-sale. Thus, one aspect of the Commission's involvement in the regulation of the hearing aid industry is to assist state law enforcement agencies in monitoring and investigating hearing aid advertising and sales practices.

¹ Kochkin, N. Sergei, MarketTrak III . . . Higher Hearing Aid Sales Don't Signal Better Market Penetration, THE HEARING JOURNAL, July 1992, pp. 47-54.

² THE HEARING JOURNAL, March 1992, at 7.

The Honorable David Pryor -- Page 2

Moreover, on the federal level, the Food and Drug Administration ("FDA") has been very active in this area. As the Committee is aware, under the 1976 Medical Device Amendments to the Food, Drug and Cosmetic Act, 21 U.S.C. § 301 et seq., the FDA plays a very important role in the regulation of the hearing aid industry. The Commission works closely with the FDA in identifying cases for enforcement action.

Pursuant to the FTC Act and the Trade Regulation Rules promulgated under that Act, the Commission's law enforcement activity in this area focuses upon unfair or deceptive acts or practices in the advertising, marketing, promotion and sale of hearing aids. The Commission has pursued law enforcement actions against a number of national or regional hearing aid manufacturers and marketers that allegedly have engaged in acts or practices that violate the Act or one of the Commission's Rules. For example, in 1991, the Commission filed complaints against two door-to-door sellers of hearing aids, charging that these companies failed to give consumers the three-day right to cancel which is required in the context of door-to-door sales by the Commission's Cooling-Off Rule.³ Marquez, Inc., doing business as Miracle-Ear Hearing Aid Center of Vineland, New Jersey, agreed to pay a \$15,000 civil penalty and was enjoined from violating the Cooling-Off Rule. The second company, Doro Lee (which does business as Brown Hearing Aid Centers), sells hearing aids throughout Texas, Louisiana, and Arkansas, usually from temporary business locations such as motels, churches and community centers. The Federal court enjoined Doro Lee from violating the Cooling-Off Rule and ordered the company to pay a \$3,000 civil penalty.

Earlier this year, the Commission brought cases against seven hearing-aid sellers with more than 30 offices in California, New York and Massachusetts,⁴ charging that these companies made false and deceptive claims in their Yellow Pages

³ 16 C.F.R. Part 429 (1993); see FTC v. Doro Lee Inc., No. CA3-91-0341 J (N.D. Tex. Feb. 13, 1991), and FTC v. Marquez Inc., No. 915-466 (D. N.J. Dec. 6, 1991). Copies of the press releases describing these cases are attached.

⁴ Center for Improved Communications, FTC Docket No. C-3433 (June 15, 1993); Sherwin Basil d/b/a Audio-Logics, FTC Docket No. C-3434 (June 15, 1993); Susan Frugone & Patricia Keane d/b/a Audio Rx Hearing Aids, FTC Docket No. C-3435 (June 15, 1993); Bay Colony Audiology Center, et al., FTC Docket No. C-3436 (June 15, 1993); Brooklyn Audiology Associates, P.C., FTC Docket No. C-3437 (June 15, 1993); Sallye B. Carpenter d/b/a Brown-Potter Hearing Aid Center, FTC Docket No. C-3438 (June 15, 1993); and Hearing Care Associates-Arcadia, et al., FTC Docket No. C-3439 (June 15, 1993).

The Honorable David Pryor -- Page 3

advertising, violating Section 5 of the FTC Act. Specifically, these cases targeted false claims that Medicare helps cover the cost of hearing aids or hearing tests. All of the cases resulted in consent orders requiring the sellers to correct future Yellow Pages ads, to post corrective information about Medicare coverage prominently in their offices or provide such information to each consumer in writing prior to purchase, and to cease misrepresenting the coverage provided by any medical insurance for any hearing-related device or service they offer. In publicizing these cases, the Commission received considerable cooperation from the American Association of Retired Persons (AARP), the Yellow Pages Publishers Association, and the American Speech-Language-Hearing Association. The Commission anticipates that these orders will deter other hearing aid sellers from using similar false and deceptive claims about medicare coverage in advertising for hearing aids and hearing test in Yellow Page directories. Copies of the press release on these seven cases are attached.

The Commission also monitors the conduct of the more than 60 hearing aid manufacturers and sellers who are the subjects of previous cease and desist orders issued by the Commission. These orders generally prohibit the respondents from making false, deceptive or unsubstantiated claims concerning the benefits, characteristics, efficacy, or uniqueness of their products. (A listing of these cases is attached.) Under Section 19 of the FTC Act, each violation of such an order can result in imposition of a civil penalty of \$10,000. Commission staff presently are conducting nonpublic investigations involving compliance with these orders by some members of the hearing aid industry.

Another way the Commission combats deceptive sales practices in the hearing aid industry is through education -- helping consumers learn how to anticipate deceptive sales schemes. In 1991, the FTC worked with AARP to develop the fact sheet, "Hearing Aids." This fact sheet describes the two basic types of hearing loss (conductive and sensorineural), offers purchase suggestions for hearing aids, and outlines federal and state standards for their sale. The FTC distributed this fact sheet through more than 10,000 media and opinion leaders, such as print and broadcast media, consumer Action Lines, the Better Business Bureau, local Chambers of Commerce, and members of the National Association of Consumer Affairs Administrators. In addition, AARP promoted the brochure to its membership. As a result, more than 115,000 copies of their publication have been distributed since its release in 1991. A copy of the fact sheet is attached.

Although the Commission receives relatively few complaints regarding alleged abuses in the hearing aid industry, those consumers who do complain to the Commission are advised by the Commission's staff about private, state and local government resources available to assist them in resolving consumer problems

The Honorable David Pryor -- Page 4

which supplements the Commission's own efforts.¹ When the complaint involves issues which are best addressed by state or local law enforcement agencies, the staff refers the complaints to the appropriate agencies.

The Commission's efforts relating to the advertising and marketing of hearing aids are but one aspect of the FTC's activities to address unfair or deceptive practices that have targeted and victimized the elderly. Other important areas of concern include our enforcement efforts relating to telemarketing fraud, consumer credit, funeral services, and the marketing of living trusts. The Commission's 1992 staff summary of FTC activities on behalf of older consumers and their families, which was submitted to the Committee in December 1992, provides more detail on the many FTC activities that directly benefit older members of our society.

The Federal Trade Commission appreciates this opportunity to provide information to the Committee about the Commission's activities, alone, in conjunction with state and local agencies, and with the FDA, to combat deceptive practices in the advertising and sale of hearing aids.

By direction of the Commission.

Janet D. Steiger
Janet D. Steiger
Chairman

Attachments

¹ The Commission generally does not resolve individual disputes but looks for a pattern of allegedly unfair or deceptive acts or practices in determining whether a law enforcement action is in the public interest.

FTC news

Federal Trade Commission Washington, D.C. 20580

FOR RELEASE: December 16, 1991

**FTC CHARGES HEARING-AID SELLER VIOLATED
DOOR-TO-DOOR SALES RULE; COMPANY AGREES
TO PAY \$15,000 CIVIL PENALTY**

The Federal Trade Commission has charged Marquez Inc., doing business as Miracle-Ear Hearing Aid Center, of Vineland, New Jersey, and its owner, Mark Marquez, with violating the FTC's Cooling-Off Rule in connection with the door-to-door sale of hearing aids. Under a proposed consent decree filed in federal court to settle the charges, Marquez would pay a \$15,000 civil penalty and be prohibited from violating the Rule in the future.

Under the FTC's Cooling-Off Rule, sales of more than \$25 made door-to-door or at places other than the seller's usual place of business can be cancelled by consumers within three business days. The seller must inform consumers of their right to cancel at the time of sale, and provide a full refund within 10 days of cancellation.

According to the complaint, Marquez failed to furnish buyers of its hearing aids with a summary notice, as required by the Rule. This notice must be on the contract at or near the place for the buyer's signature, and inform the buyer of his or her right to cancel.

The complaint also charges that Marquez failed to furnish buyers with the notice of cancellation forms required by the Rule. Under the Rule, the seller must furnish the customer with two copies of this completed form, which explains the right to cancel, details the procedure for cancelling, and contains the name and address of the seller and the date by which the cancellation must be made.

The FTC's New York Regional Office handled the investigation. At the FTC's request, the Department of Justice filed the complaint and proposed consent decree on Dec. 6 in the U.S. District Court for the District of New Jersey, in Camden. The decree requires approval by the court.

NOTE: A consent decree is for settlement purposes only and does not constitute admission of a law violation. When approved by the judge, consent decrees have the force of law.

The FTC's Office of Consumer and Business Education has a fact sheet for consumers on the Cooling-Off Rule.

Copies of the complaint and the proposed consent decree will be available shortly. Copies of the Facts for Consumers are available from the FTC's Public Reference Branch, Rm. 130, 6th Street and Pennsylvania Ave. N.W., Washington, D.C. 20580; 202-326-2222; TTY 202-326-2502.

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MEDIA CONTACT: Howard Shapiro, Office of Public Affairs,
202-326-2181

STAFF CONTACT: Michael J. Bloom, New York Regional Office,
150 William Street, Suite 1300
New York, NY 10038
212-264-1207

(Civil Action No. 915-466)

(FTC File No. 892 3161)

(Marquez)

FTC news

Federal Trade Commission Washington, D.C. 20580

FOR IMMEDIATE RELEASE: February 14, 1991

**FTC FILES FEDERAL COURT COMPLAINT CHARGING
HEARING-AID SELLER WITH VIOLATING
COOLING-OFF RULE**

The Federal Trade Commission has charged Doro Lee Inc., which does business as Brown Hearing Aid Centers, of Orange, Texas, and Leroy Brown, its president, with violating the FTC's Cooling-Off Period for Door-to-Door Sales Rule in connection with the sale of hearing aids. The Commission asked a federal court to prohibit future violations of the Rule and to order the company to pay a civil penalty.

Brown Hearing Aid Centers sell hearing aids throughout Texas, Louisiana, and Arkansas, usually from temporary business locations such as motels, churches, and community centers.

Under the Rule, sales of more than \$25 made door-to-door or at places other than the seller's usual place of business may be cancelled up to three business days after the sale. The Rule has most often been applied to sales made door-to-door, but it also covers transactions made at temporary business locations. The seller must provide both a written notice of the purchaser's cancellation rights and a form for the consumer to use to cancel the contract and get a refund.

According to the complaint, Brown has failed to furnish buyers with the Summary Notice that informs the buyer of his or her right to cancel, as required by the Rule. The Notice must be on the contract at or near the place of the buyer's signature.

The complaint also charges that Brown failed to furnish buyers with the Notice of Cancellation Form required by the Rule. Under the Rule, the seller must furnish the customer with two copies of this completed form, which explains the right to cancel, details the procedure for cancelling, and contains the name and address of the seller and the date by which the cancellation must be made.

In addition, Brown misrepresented the buyer's right to cancel, the complaint charges.

The FTC's Dallas Regional Office handled the investigation. At the FTC's request, the Department of Justice filed the complaint in the U. S. District Court for the Northern District of Texas, Dallas Division, on February 13.

NOTE: The Commission files a complaint when it has "reason to believe" that the law has been or is being violated, and it appears to the Commission that a proceeding is in the public interest. The complaint is not a finding or ruling that the defendant has actually violated the law. The case will be decided by the court.

Copies of the complaint are available from the FTC's Public Reference Branch, Room 130, 6th St. and Pennsylvania Ave. N. W., Washington, D. C. 20580; 202-326-2222; TTY 202-326-2502.

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MEDIA CONTACT: Howard Shapiro, Office of Public Affairs,
202-3326-2176

STAFF CONTACT: Maridel Morgan, Dallas Regional Office,
214-767-5503

(Civil Action No. CA3-91-0341 J)

(Brownaid)



OFFICE OF PUBLIC AFFAIRS
(202) 326-2180

UNITED STATES OF AMERICA
FEDERAL TRADE COMMISSION
WASHINGTON, D.C. 20580

FOR YOUR INFORMATION.....JUNE 17, 1993

The Federal Trade Commission has given final approval to consent agreements with seven hearing-aid sellers with more than 30 offices in California, New York and Massachusetts. The agreements settle charges that the sellers made false and deceptive claims in Yellow Pages advertisements that Medicare helps cover the cost of hearing aids or hearing tests. (By law, Medicare does not cover the cost of hearing aids, nor does it cover the costs of hearing tests when they are conducted to prescribe or fit hearing aids.)

The settlements are with:

-- Sherwin Basil, who does business as Audio Logics, and who has offices in Long Beach and Santa Ana, California;

-- Sallye B. Carpentier, who does business as Brown-Potter Hearing Aid Center, and whose office is located in Long Beach, California;

-- Susan Frugone and Patricia Kean, who are partners doing business as Audio Rx Hearing Aids, with offices in Los Angeles and Lawndale, California;

-- Hearing Care Associates and Gregory Frazer, who is an owner or partner in each of the company's approximately 20 offices in cities in southern California, including in Arcadia, Glendora, Los Angeles, Panorama City and Alhambra;

-- Brooklyn Audiology Assocs., P.C. and company officer Richard Kaner, with three offices in Brooklyn, New York;

-- Center for Improved Communications and company officer Jack Brown, with two offices in Brooklyn, New York; and

-- Bay Colony Audiology Center and company officer David Citron, with its office in South Weymouth, Massachusetts.

- more -

(Hearing Aid Sellers--06/17/93)

Under the final consent orders, the respondents are prohibited from misrepresenting that Medicare or any other type of medical insurance will pay for the cost of any hearing-related devices or services. In addition, each respondent must send a certified letter, within 15 days, to the publisher of each Yellow Pages directory in which it made the challenged representations. The letters will state that any claims that Medicare will pay for the cost of hearing aids are to be eliminated from the next and subsequent editions, and that future claims regarding Medicare coverage for hearing tests must be qualified with a disclosure that such tests must be ordered in advance by a physician for diagnostic purposes. Copies of the consent order will accompany the letters.

The orders also require the sellers to make specifically-worded disclosures to their customers, for the next two years, about the limits on Medicare coverage for hearing aids and hearing tests.

The consent agreements were placed on the public record on March 24, and issued in final form on June 15. (Docket Nos. C-3433 - 3439) The Commission vote to issue the orders was 5-0.

NOTE: A consent agreement is for settlement purposes only and does not constitute admission of a law violation. When the Commission issues a consent order on a final basis, it carries the force of law with respect to future actions. Each violation of such an order may result in a civil penalty of up to \$10,000.

A press release summarizing the complaints and consent agreements was issued at the time the Commission accepted the consent agreements for public comment. Copies of that release and of the final orders are available from the FTC's Public Reference Branch, Room 130, 6th Street & Pennsylvania Avenue, N.W., Washington, D.C. 20580; 202-326-2222; TTY for the hearing impaired 202-326-2502.

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MEDIA CONTACT: Bonnie Jansen, Office of Public Affairs
 202-326-2161

STAFF CONTACT: Eileen Harrington, Bureau of Consumer Protection
 202-326-3127

(FTC File No. 922 3037)
(hearing2)

FTC news

Federal Trade Commission Washington, D.C. 20580

FOR RELEASE: MARCH 24, 1993

SEVEN HEARING-AID SELLERS SETTLE FTC CHARGES OF FALSE CLAIMS ABOUT MEDICARE COVERAGE

In cases against seven hearing-aid sellers with more than 30 offices in California, New York and Massachusetts, the Federal Trade Commission today launched an attack against false and deceptive claims in Yellow Pages advertisements that Medicare -- the federal medical insurance program for those over 65 -- helps cover the cost of hearing aids or hearing tests. All of the sellers have agreed to settle the FTC charges by signing proposed consent orders that would require them to correct future Yellow Pages ads, prominently post corrected information about Medicare coverage in their offices or provide it to consumers prior to purchase, and prohibit them from misrepresenting the coverage provided by any medical insurance for any hearing-related device or service they offer in the future.

Approximately 26 million people in the United States are hearing impaired, and nearly one-fourth of them wear some form of hearing instrument, FTC staff said. In addition, more than 60 percent of hearing aids in the country are purchased by those over age 65. In 1991, according to industry sources, approximately 1.42 million hearing aids were sold, with an average retail price of \$667.

By law, Medicare does not cover the cost of hearing aids under any circumstances, nor does it cover hearing tests, even if conducted by audiologists or physicians, when the tests are conducted for the purpose of prescribing or fitting hearing aids. Medicare does help cover the cost of hearing tests when they are ordered by physicians to diagnose some type of medical problem, however.

The companies and their officers who have agreed to settle the FTC charges announced today are:

- Sherwin Basil, who does business as Audio Logics, and who has offices in Long Beach and Santa Ana, California;
- Sallye B. Carpentier, who does business as Brown-Potter Hearing Aid Center, and whose office is located in Long Beach, California;
- Susan Frugone and Patricia Kean, who are partners doing business as Audio Rx Hearing Aids, with offices in Los Angeles and Lawndale, California;
- Hearing Care Associates and Gregory Frazer, who is an owner or partner in each of the company's approximately 20 offices in cities in southern California, including in Arcadia, Glendora, Los Angeles, Panorama City and Alhambra;
- Brooklyn Audiology Assocs., P.C. and company officer Richard Kaner, with three offices in Brooklyn, New York;
- Center for Improved Communications and company officer Jack Brown, with two offices in Brooklyn, New York; and
- Bay Colony Audiology Center and company officer David Citron, with its office in South Weymouth, Massachusetts.

According to the FTC complaints detailing the charges, the respondents allegedly placed ads for hearing aids in various Yellow Pages directories. The ads contained statements or used the word "Medicare" in a way that allegedly represented Medicare will pay for the cost of the respondents' hearing aids, hearing tests or both. For example, the ads included statements such as:

- "Hearing Aid Evaluations and Sales ... Medicare Assignment Accepted;"
- "...Sales and Service ... All Major Brands ... Medicare ... welcome;" and
- "Hearing Aid Center ... U.S. Government Plans Accepted."

The alleged representations that Medicare will pay for hearing aids are false and misleading, the FTC charged. Further, in five cases, the FTC charged that it was deceptive for the defendants, in advertising that Medicare will pay for hearing tests, to fail to disclose that Medicare helps pay only for hearing tests ordered in advance by a physician for diagnostic purposes.

The proposed consent agreements to settle these charges would prohibit the respondent hearing-aid sellers from misrepresenting that Medicare or any other type of medical insurance will pay for the cost of any hearing-related devices or services. Second, each respondent would be required to send a certified letter, within 15 days after the settlements are approved, to the publisher of each Yellow Pages directory in which it made the challenged representations. The letter would state that any claims that Medicare will pay for the cost of hearing aids are to be eliminated from the next and subsequent editions. Further, the letter would state that claims regarding Medicare coverage for hearing tests must be qualified with a disclosure that hearing tests must be ordered in advance by a physician for diagnostic purposes. A copy of the consent order would have to be included with each letter.

The settlements also would require the sellers to post prominently in the reception area of each of their offices and in each examination room a specifically-worded notice making clear the limits on Medicare coverage for hearing aids and hearing tests. Alternatively, the respondents could provide the notice to each customer -- and obtain the customer's signature on it -- prior to any discussion about the customer's hearing problem. These notification requirements would expire after two years.

Finally, the proposed consent agreements contain various reporting requirements to assist the FTC in monitoring the respondents' compliance.

The Commission vote to accept the proposed consent agreements for public comment was 5-0. They will be published in the Federal Register shortly and will be subject to public comment for 60 days, after which the Commission will decide whether to make them final. Comments should be addressed to the FTC, Office of the Secretary, 6th Street and Pennsylvania Avenue, N.W., Washington, D.C. 20580.

NOTE: Consent agreements are for settlement purposes only and do not constitute admissions of law violations. When the Commission issues a consent order on a final basis, it carries the force of law with respect to future actions. Each violation of such an order may result in a civil penalty of \$10,000.

The FTC has developed a fact sheet for consumers who are considering purchasing hearing aids. The "Hearing Aids" fact sheet describes federal and state standards for sales of hearing aids, and offers tips for consumers. Free copies of this fact sheet, as well as copies of the complaints and proposed consent agreements, are available from the FTC's Public Reference Branch, Room 130, at the above address; 202-326-2222; TTY for the hearing impaired 202-326-2502.

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MEDIA CONTACT: Bonnie Jansen, Office of Public Affairs
 202-326-2161

STAFF CONTACT: Collot Guepard, Bureau of Consumer Protection
 202-326-3338

(FTC File No. 922 3037) (hearing)

FEDERAL TRADE COMMISSION ACTIVITIES INVOLVING THE
SALE OF HEARING AIDS AND/OR THE QUALIFICATIONS OF
HEARING AID SELLERS, EXCLUDING CASES INVOLVING ONLY
ISSUES OF COMPETITION AND TRADE PRACTICE RULES

1. Sonotone Corporation, 88 FTC 368 (1976). Consent order requiring an Elmsford, N.Y. manufacturer of hearing aids to cease making false, deceptive and unsubstantiated claims and representations concerning the benefits, characteristics, efficacy and uniqueness of its products.
2. Beltone Electronics Corporation, 88 FTC 336 (1976). Consent order requiring a Chicago, Ill., hearing aid manufacturer to cease misrepresenting the uniqueness, benefits, characteristics and efficacy of its products.
3. Dahlberg Electronics, Inc., 88 FTC 319 (1976). Consent order requiring a Minneapolis, Minn., manufacturer of hearing aids and hearing aid products to cease misrepresenting the benefits, performance characteristics, efficacy and uniqueness of its products.
4. Radioear Corporation, 88 FTC 308 (1976). Consent order requiring a McMurray, Penn., hearing aid manufacturer to cease making false, deceptive and unsubstantiated claims or representations regarding the benefits, characteristics, efficacy and/or uniqueness of its products.
5. Maico Hearing Instruments, Inc., 88 FTC 298 (1976). Consent order requiring a Minneapolis, Minn., hearing aid manufacturer to cease misrepresenting the benefits, performance characteristics, efficacy and uniqueness of its merchandise.
6. Qualitone, Inc., 88 FTC 287 (1976). Consent order requiring a Minneapolis, Minn., hearing aid manufacturer to cease misrepresenting the benefits, performance characteristics, efficacy and uniqueness of its products.
7. M & W Electronics, Inc., 84 FTC 1287 (1974). Consent order requiring a Dallas, Tex., retailer of hearing aids to cease misrepresenting the usual and customary retail price of its merchandise.
8. The Telex Corporation, 79 FTC 61 (1971). Consent order requiring a Tulsa, Oklahoma, manufacturer of hearing aids to cease and desist from (1) representing that its hearing aid is a new invention, is invisible when worn, or will benefit all persons with hearing, and (2) misrepresenting in any manner (a) the nature or purpose of its business, or (b) the merits and effectiveness of its hearing aids. The order also requires respondent affirmatively to disclose that it is engaged in the manufacture and distribution of hearing aids for sale to the public, and that persons who reply to advertisements may be contacted by salesmen, or otherwise, for the purpose of inducing them to purchase a hearing aid.
9. Community Hearing Center, Inc., 78 FTC 1265 (1971). Consent order requiring a Providence, Rhode Island, retail seller of hearing aids to cease advertising that (1) it sells a hearing aid which is a new invention or involves a new mechanical or scientific principle, (2) its hearing aid which utilizes bone-conduction principles will be beneficial to an individual regardless of the type or degree of the individual's hearing impairment, and (3) its hearing aids are invisible or indiscernible when worn. The order also requires respondent affirmatively to disclose in advertising that its business is the sale of hearing aids.
10. Mather Hearing Aid Distributors, Inc., 78 FTC 709 (1971). Order requiring three sellers of hearing aid "devices" to cease representing that their hearing aids (1) involved a new scientific principle, (2) would be helpful regardless of the hearing disability, (3) prevent deafness, (4) transform high tones to lower tones, (5) are invisible when worn, (6) fit entirely within the ear canal, and (7) need no batteries. Respondents also were forbidden from representing that hearing aids for both ears were more beneficial than for one and that their sales personnel had medical or scientific training. The order required respondents affirmatively to disclose in advertising that their business is the sale of hearing aids.

11. Lloyd Hearing Aid Corporation, 77 FTC 1582 (1970). Consent order requiring a Rockford, Ill., distributor of hearing aid and parts and accessories thereof to cease (1) misrepresenting that respondent sells "America's Largest Selection of Hearing Aids," (2) misrepresenting the number of times a hearing aid battery can be recharged, (3) misrepresenting that its hearing aids are the most powerful on the market, (4) exaggerating the savings to customers, (5) misrepresenting that any hearing aid it sells is a new invention, (6) failing to disclose the nature of its guarantees, and (7) failing to disclose that diagnosis of hearing defects by mail is inadequate.
12. Mountain States Hearing Service, Inc., 77 FTC 640 (1970). Consent order requiring a Billings, Montana, dealer and distributor of hearing aids to cease (1) advertising that it is a multiple city firm, that it conducts research in hearing disability, and that its devices will restore "normal" hearing or prevent its deterioration, and (2) claiming that its salesmen have been scientifically trained, or misrepresenting in any way its business, sales personnel, or efficacy of its hearing aids. Respondent was required affirmatively to disclose in advertising that its business is the sale of hearing aids.
13. Minnesota Hearing Aid & Optical Centers, Inc., and South Dakota Hearing Aid Center, Inc., Assurance of Voluntary Compliance #2150 (1970). Hearing aid sellers agreed not to represent that their hearing aids could correct all types of hearing loss, that they could correct all types of "nerve deafness," that no batteries were required for operation, or that non-operative replicas were in fact the real models. Respondents also agreed not to use the word "prescribed" unless in fact the hearing aid was made according to a physician's prescription for a particular purchaser, to use the word "new" more than one year after the introduction of a significant improvement over an older device, or to use the word "guarantee" unless the terms of the guarantee are specified.
14. Sonotone Corporation, Assurance of Voluntary Compliance #2109 (1970). Hearing aid manufacturer agreed not to conduct a "National Hearing Aid Census" which revealed information to be used by it in the marketing of hearing aids unless it disclosed conspicuously that it was in the business of distributing hearing aids.
15. Maryland Hearing Aid Service, Assurance of Voluntary Compliance #2093 (1970). Hearing aid seller agreed to stop representing, among other things, (1) that the hearing aids it offered for sale were a "new" invention or involved a new mechanical or scientific principle, when such is not the fact; (2) that a hearing aid offered for sale eliminates all background noises; and (3) that any hearing aid is a comparable value to a higher priced aid unless it has determined that the aids compared are identical in all material and scientific respects.
16. Medical Supplies, Inc., Assurance of Voluntary Compliance #2066, (1969). Hearing aid seller agreed to cease falsely advertising that its hearing aid was a new invention, to cease representing that it is accredited by a medical or scientific organization, and to cease advertising "free models" of hearing aids when such models were only inactive replicas.
17. Fidelity Electronics, Ltd., Assurance of Voluntary Compliance #1883 (1969). Hearing aid manufacturer agreed to cease falsely advertising that its hearing aids were based on a new scientific principle, that they compensated for a greater degree of hearing loss than they did, or that they were more effectively concealed than they were. Respondent also agreed not to represent that a non-operating model of a hearing aid was a complete operating model.
18. North American Philips Company, Inc., Assurance of Voluntary Compliance #1632 (1969). Hearing aid manufacturer agreed not to represent that its hearing aids were more effectively hidden when worn than was the fact or that they compensate for a greater degree of hearing loss than was the fact.
19. Washington Hearing Center, Assurance of Voluntary Compliance #1557 (1969). Two hearing aid sellers agreed not to use any name which may indicate a government affiliation or to advertise particular product features as providing "New Help for Hard of Hearing."

20. True Hearing Center, Assurance of Voluntary Compliance #1423 (1968). Hearing aid seller agreed not to advertise that its hearing aids helped "nerve deafness," and not to use the name "true Hearing Center" as the name of a commercial enterprise.
21. Buchanan Hearing Aid Co., Inc., Assurance of Voluntary Compliance #1172 (1968). Hearing aid seller agreed to change the wording of its advertisements for hearing aids generally so that "miracle" was changed to "marvel," "can hear" became "may hear," and "nerve deafness" became "mild nerve deafness." Respondent also agreed to supply an offer of a free trial in the case of a hearing aid model that might have been deceptive. Representations that its hearing aids were "all but hidden" became representations that they were "nearly hidden."
22. Goldentone Electronics, Inc., Assurance of Voluntary Compliance #1170, (1968). Hearing aid manufacturer agreed, among other things, not to represent that its hearing aids were more effective or compensated for a greater degree of hearing loss than was the fact.
23. Audivox Hearing Aids, Assurance of Voluntary Compliance #1104 (1968). Hearing aid manufacturer agreed not to represent that its hearing aids were smaller or better concealed than was the case, to substitute "may hear" for "can hear," and to disclose, in the case of hearing aids that work on the bone-conduction principle, that in many cases their hearing aids will not be suitable.
24. Dahlberg Electronics, Inc., Assurance of Voluntary Compliance #1100 (1968). Hearing aid manufacturer agreed to reword its ads for hearing aids, generally so that "nerve deafness" was changed to "mild nerve deafness," "hear" became "hear more clearly," and "help" became "may help."
25. M. W. Kitzik Hearing Aids: Assurance of Voluntary Compliance #1099 (1968). Hearing aid seller agreed not to represent that his hearing aids were more effective or cured a greater degree of hearing loss than was the case, or that they were smaller than was the case, or that the FTC had allotted respondent a wave length for the instrument.
26. Zenith Radio Corporation, Assurance of Voluntary Compliance #1088 (1968). Hearing aid manufacturer agreed to cease advertising that its hearing aids would be so powerful that users would not miss a word, that it had a model that would treat "nerve deafness," or that it had a line fully effective for moderate hearing losses, when such was not the fact.
27. Sonotone Corporation, Assurance of Voluntary Compliance #1064 (1968). Hearing aid manufacturer agreed, among other things, not to represent that its hearing aids were smaller or better hidden than was indeed the fact.
28. Otarion Electronics, Inc., Assurance of Voluntary Compliance #1024 (1968). Hearing aid manufacturer was ordered to cease making the following representations: (1) "You can wear it without even your closest friends realizing it's a hearing aid"; (2) "a recently patented invention"; (3) "nerve deafness"; (4) "slip it into your ear and hear again." Respondent also agreed not to advertise that its hearing aids worked without batteries or other visible mechanisms, unless it disclosed that the bone-conduction principle it used was not applicable to everyone.
29. National Hearing Aid Centers, Inc., Assurance of Voluntary Compliance #687 (1967). Hearing aid seller agreed to cease to represent that its product was "positive help for nerve deafness," and that one could "slip it into your ear and hear again instantly." It also agreed to cease offering "free" gifts as a means of obtaining leads.
30. Mace Warner Co., Inc., Assurance of Voluntary Compliance #646 (1967). Hearing aid seller agreed to cease making representations that, in effect, stated that its hearing aid was able to relieve "nerve deafness," (ability to hear sounds but not understand them).

31. Taylor Hearing Aid Center, Assurance of Voluntary Compliance #609 (1967). Bearing aid seller, seller of a "hearing aid special," agreed to cease using the following representations in its advertisements: "hear again clearly," "nerve deafness," "sounds are amplified loudly and clearly."
32. Maico Electronics, Inc., Assurance of Voluntary Compliance #206 (1966). Hearing aid manufacturer agreed to cease sending out a mailing posing as a "Senior Citizens Survey," which did not identify the seller as a manufacturer of hearing aids.
33. Regal Audio Instruments, 66 FTC 989 (1964). Consent order requiring distributors of "Ultima" hearing aids in Buffalo, N.Y., to cease representing falsely in advertising that the device was unconditionally guaranteed, that the "Ultima" hearing aid had a permanent source of power which would never need replacement, that it would bring every wearer's hearing up to normal levels, and that it was approved and endorsed by the Federal Trade Commission.
34. Sonotone Corporation, 56 FTC 1101 (1960). Consent order requiring an Elmsford, New York, manufacturer of hearing aids to cease representing in advertising that its hearing aids were cordless, buttonless, and invisible.
35. The Dahlberg Company, 56 FTC 1098 (1960). Consent order requiring a Minneapolis, Minn., manufacturer to cease representing (1) that its "Miracle Ear," "Solar Ear," and "Optic Ear" hearing aids were buttonless, cordless, and invisible, and (2) that the "Miracle Ear" device provided equally good hearing from all directions and was smaller than was the fact.
36. Beltone Hearing Aid Company, 56 FTC 387 (1959). Consent order requiring a Chicago, Ill., manufacturer of hearing aids to cease representing in advertising (1) that its "Hear-N-See" and "Shinette" hearing aid devices had no attached buttons, wires, or cords, were invisible, and were hidden in eyeglasses, (2) that its "Invisible" hearing aid was in fact invisible, and (3) that their advertising booklets were offered as a public service to the hard of hearing.
37. Audivox, Inc., et al. 56 FTC 215 (1959). Order requiring a Boston, Mass., manufacturer to cease representing in advertising that its air-conduction hearing aids (1) had no buttons, wires, or cords attached, (2) were invisible or concealed, and (3) that its advertising booklet was distributed as a public service.
38. Zenith Radio Corp., 55 FTC 2133 (1959). Stipulation requiring an Illinois manufacturer of hearing aids to cease (1) comparing its hearing aids to discontinued models of competitor's hearing aids without disclosure of this fact, and (2) falsely disparaging its competitors' products.
39. Qualitone Hearing Aid Company, Inc., 55 FTC 120 (1958). Consent order requiring a Minneapolis, Minn., manufacturer of hearing aids to cease representing (1) that their hearing aids were cordless, invisible, and required nothing in the ear, and (2) that the former was completely contained in a pair of eyeglasses.
40. Tonemaster Manufacturing Company, 55 FTC 1750 (1959). Consent order requiring manufacturers in Peoria, Ill., to cease advertising that their hearing aids were cordless, required nothing in the ear, and were invisible.
41. Otarion, Inc., 54 FTC 382 (1957). Consent order requiring a manufacturer of hearing aids in Dobbs Ferry, N.Y., and its franchise distributor in the District of Columbia, to cease representing that their "Listener" hearing aid was cordless, could not be seen, required nothing in either ear, and was completely contained in and could not be distinguished from ordinary eyeglasses.
42. Forrest A. Jones, d/b/a Oregon Hearing Center, 52 FTC 1192 (1956). Consent order requiring two hearing aid sellers to cease representing that its hearing aids (1) are invisible; (2) will provide hearing to the deaf; (3) will fit any ear; (4) have the approval of the American Medical Association; and (5) that its bone-conduction aids were a recent invention, invisible, and would enable deaf persons to hear as well as do normal-hearing persons.

43. Oklahoma College of Audiometry, 52 FTC 558 (1955). Consent order requiring an Oklahoma City seller of a correspondence course in audiometry (the fitting of hearing aids) to cease representing that students making a passing grade would receive a diploma of Doctor of Audiometry, indicated by the letters "D.A."
44. Anthony W. Hagedorn, d/b/a Buchanan Hearing Aid Company, 51 FTC 55 (1954). Consent order requiring a seller of hearing aids to cease representing that the device (1) will fit into the ear canal of all persons, (2) is hidden and out of sight when in the ear canal, (3) will fit all hearing aids, and (4) has been accepted by the American Medical Association.
45. Dictograph Products, Inc., 50 FTC 179 (1953). Consent order requiring a manufacturer of "Acousticon" hearing aids in Jamaica, N.Y., to cease representing (1) that booklets published by it contain a report on hearing aids by the U.S. Government or any branch thereof, (2) that its hearing aids are the only ones on the market that are satisfactory, (3) that its hearing aids are recommended by the United States Government or any branch thereof, and (4) that competitors' hearing aids have not been improved in recent years.
46. The Dahlberg Company, 50 FTC 938 (1954). Consent order requiring a Minneapolis, Minn., retailer and distributor of hearing aid devices to cease disseminating any advertisement which represents that said device: (1) will fit the ear canals of all persons, (2) is hidden or out of sight when inserted in the ear canal, (3) has been accepted by the American Medical Association, and (4) will fit all hearing aids.
47. Rochester Acoustical Laboratories, 50 FTC 1138 (1953). Stipulation requiring a Minnesota corporation to cease representing (1) that its hearing aids which use an earmold or tube leading to the ear include nothing in or leading to the ear, and (2) that its hearing aids are invisible or cannot be seen.
48. Audivox, Inc., 50 FTC 1151 (1953). Stipulation requiring a Massachusetts manufacturer and seller of hearing aids to cease representing (1) that any of its sales literature or other data available to the general public is "confidential"; (2) that any advertising material is impartial scientific information on hearing aids; and (3) that any advertising material is distributed as a public service.
49. Miracle Hearing Aid, Inc. et al., 49 FTC 1410 (1953). Order that a corporation engaged in the interstate sale and distribution of a device designated "Miracle Hearing Aid" designed for insertion in the external auditory canal cease falsely representing (1) that said device was a hearing aid and that by its use the hearing of deaf persons, or those with a partial or complete loss of hearing, would be benefited; (2) that said device had been approved by physicians; and (3) cease failing to disclose material facts with respect to the consequences resulting from the use of the device under usual conditions.
50. National College of Audiometry, 48 FTC 1149 (1952). Order requiring an Illinois correspondence school of audiometry to cease representing that it was empowered to grant academic degrees.
51. The Elmo Company, Inc., 48 FTC 1379 (1952). A corporation engaged in the interstate sale and distribution to the public of a combination of drug preparations and a device referred to by it as "Home Treatment"; was ordered to cease from falsely representing (1) that use of its said preparations and device in combination, as directed, would cure or constitute an effective treatment for deafness and impaired hearing, (2) that its said method of treatment was based on the findings of accepted medical authorities; and (3) that said preparations and device might be used safely and without harm to the user.
52. Telex, Inc., 48 FTC 1625 (1951). Stipulation requiring a Minnesota manufacturer of hearing aids to cease representing, among other things, that through the use of such words and terms as "hear secretly," "hidden hearing" and "invisible hearing," or otherwise, that no part of its hearing aid devices, as worn, is visible or can be seen.

53. The Microtone Co.,, 48 FTC 1664 (1952). Stipulations requiring a Minnesota corporation to cease representing, among other matters, that their hearing aids are invisible or cannot be seen.
54. Beltone Hearing Aid Co., 48 FTC 1671 (1952). Stipulation requiring an Illinois hearing aid manufacturer to cease representing (1) that the sizes or weights of their hearing aid devices are different from what is in fact the case; (2) that any of its hearing aid devices which employ an earmold or a tube include nothing worn in or leading to the ear; (3) that their hearing aid devices give "full-tone hearing" or the "richest" or "clearest" hearing; (4) that their hearing aid devices eliminate fading in and out; (5) that their hearing aid devices will enable the hopelessly deaf to hear again; (6) that their hearing aid devices embody new or different electronic principles from those found in other hearing aid devices; (7) through the use of such words, terms, and phrases such as "hides deafness," "conceals deafness," "even close friends won't know you're wearing a hearing aid" or otherwise, that any device which is not completely concealed when worn by any user is invisible or cannot be seen; (8) that by means of their hearing aid devices, a user can prevent his hearing loss from becoming progressively worse; and (9) that their hearing aid devices require less equipment than all parts essential to the functioning thereof.
55. Dictograph Products, Inc., 48 FTC 1672 (1952). Stipulation requiring a New York hearing aid manufacturer to cease representing, among other things, (1) that certain of its hearing aids employ a new or different principle, duplicate the functions of the human ear, or duplicate nature's way to hear, provide directional hearing, and enable one to hear again regardless of the cause of impaired hearing; (2) that any device which is not completely concealed when worn by any user is invisible or cannot be seen; (3) that any of its hearing aid devices which employ an earmold or a tube include nothing worn in or leading to the ear; (4) that it conducts "hearing clinics" or employs "hearing specialists" or "hearing experts"; (5) that it conducts a "public education department"; and (6) that its hearing aid devices employ no cords, unless it is clearly disclosed that the cord eliminated is the standard receiver cord.
56. Sonotone Corp., 48 FTC 1673 (1952). Stipulation requiring New York hearing aid manufacturer to cease representing (1) that any device which is not completely concealed when worn by any user is invisible or cannot be seen; (2) that any of its hearing aid devices which employ an earmold or a tube include nothing worn in or leading to the ear; (3) that there is no button or receiver in the ear, unless it is clearly disclosed that the bone-conduction receiver is worn behind the ear; (4) that its hearing aid devices require less equipment than all parts essential to the functioning thereof; and (5) that use of its hearing aid devices will benefit persons who have no residual hearing.
57. Otarion, Inc., 48 FTC 1678 (1952). Stipulation requiring an Illinois hearing aid manufacturer to cease representing (1) that any device which is not completely concealed when worn by any user is invisible or cannot be seen; (2) that any of its hearing aid devices which employ an earmold or a tube include nothing worn in or leading to the ear; and (3) that its hearing aid devices are only half the size of most hearing aids.
58. The Maico Co., 48 FTC 1679 (1952). Stipulation requiring a Minnesota hearing aid manufacturer to cease representing (1) that any device which is not completely concealed when worn by any user is invisible or cannot be seen; (2) that any of its hearing aid devices which employ an earmold or a tube include nothing worn in or leading to the ear; and (3) that its hearing aid device is a "revolutionary invention."
59. American Sound Products, Inc., 48 FTC 1682 (1952). Stipulation requiring an Illinois hearing aid manufacturer to cease representing (1) that any device which is not completely concealed when worn by any user is invisible or cannot be seen; (2) that any of its hearing aid devices which employ an earmold or a tube include nothing worn in or leading to the ear; (3) that its hearing aid devices require less equipment than all parts essential to the functioning thereof; (4) that its hearing aid devices are smaller or more powerful than all other hearing aid devices, with many other hearing aid devices being 2 or 3 times as large.

60. American Earphone Co., 47 FTC 1699 (1950). Stipulation requiring a New York corporation to cease representing that its hearing aid (1) magnifies ordinary conversation or musical tones without any distortion; (2) embodies a new acoustical principle; or (3) is an effective aid for anyone having a loss of hearing sufficient to require the use of a hearing aid.
61. Edward Baum, 46 FTC 179 (1949). Order requiring the seller of the "Mega-Ear-Phone" to cease representing, among other things, (1) that it relieved deafness, eliminated head noises, and enabled a deaf person to hear irrespective of the cause and degree of deafness; (2) that its use would restore and improve hearing.
62. C. L. Hofmann Corp., 45 FTC 894 (1949). Stipulation requiring a Pennsylvania corporation to cease representing that its hearing aid utilized any of the scientific principles involved in radar.
63. Mears Radio Hearing Device Corp., 34 FTC 1658 (1942). Stipulation requiring a hearing aid manufacturer to cease representing (1) that its hearing aid is better suited to supply the hearing aid needs of persons regardless of the degree and kind of their hearing afflictions; (2) that it will assure all deaf or partially deaf persons clear, natural, and understandable sounds or will assure immeasurably better hearing under all conditions and on all occasions; (3) that it will retard deafness by stimulating and activating the ossicles in the middle ear, or lead to improvement in hearing by stimulating or exercising the organs of hearing; and (4) that it is an entirely new hearing aid quite different from any other on the market or that it is the lightest or smallest hearing aid now marketed.
64. C. L. Hofmann Corp., 34 FTC 1567 (1941). Stipulation requiring a hearing aid manufacturer to cease representing, among other things, that its hearing aids will enable the user to hear naturally or to hear and understand everything that is said or sung wherever it may be used, regardless of the degree of the individual user's hearing impairment, or that it will assure the elimination of all auditory handicaps under all conditions of its use.
65. Better Hearing, Inc., 22 FTC 920 (1936). Stipulation requiring a hearing aid seller to cease misrepresenting the experience and size of its organization.
66. Mears Radio Hearing Device Corporation, 18 FTC 144 (1934). Order requiring a hearing aid manufacturer to cease representing that its device would aid hearing by exercising the ear muscles, would cure "head noises," and would cure people who were born deaf or had been deaf for 25 years, when in fact the treatment had long ago been tested, found worthless and dangerous, and discarded by otologists.

facts for Consumers

Federal Trade Commission • November 1992

Hearing Aids

fast facts

- A hearing aid is an electronic device that picks up sound waves with a tiny microphone.
- Because a hearing aid is an amplification device, you must have some hearing to benefit from its use.
- No single hearing aid is right for everyone.
- Be wary of advertisements for hearing aids that play down the need for a medical examination and a hearing test.
- Get a hearing evaluation from a hearing aid dispenser or an audiologist.

Bureau of Consumer Protection
Office of Consumer &
Business Education
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Produced in cooperation with the American Association of Retired Persons

More than 21 million Americans suffer from some type of hearing impairment. Fortunately, many of these people can benefit from the use of a hearing aid. However, hearing aids cannot work for everyone. Those who can be helped need to be carefully fitted. This brochure provides information about hearing loss and things to look for when shopping for a hearing aid. It stresses the importance of a medical exam and the value of a trial period.

Types of Hearing Loss

The two basic types of hearing loss are conductive and sensorineural. Conductive hearing loss involves the outer and middle ear. It can result from a blockage of wax, a punctured eardrum, birth defects, ear infections, or heredity. Usually, conductive hearing loss can be corrected medically or surgically.

Sensorineural, or "nerve" hearing loss involves damage to the inner ear. It can be caused by aging, prenatal and birth-related problems, viral and bacterial infections, heredity, trauma (such as a severe blow to the head), exposure to loud noises, the use of certain drugs, fluid buildup in the inner ear, or a benign tumor in the inner ear. Only in rare cases can sensorineural hearing loss be medically or surgically corrected. It is the type of hearing loss that is most commonly managed with a hearing aid.

Sensorineural hearing loss can affect selective portions of a person's range of hearing. Therefore, the degree of hearing loss and the specific levels of pitch (frequencies) affected will vary from person to person. Even in instances where the pattern of the loss is the same, the degree of sound clarity may vary from person to person or may differ between ears for one individual. As a result, individuals suffering from sensorineural hearing loss often require

a hearing aid tailored to the specific sensitivity and the pattern of hearing loss.

Purchase Suggestions

A hearing aid is an electronic device that picks up sound waves with a tiny microphone. The microphone makes weaker sounds louder and sends them to the ear through a tiny speaker. Because a hearing aid is an amplification device, a person must have some hearing to benefit from its use. In addition, because hearing loss has a variety of patterns and degrees of severity and affects people in different ways, no single hearing aid is right for everyone.

The Federal Trade Commission (FTC) offers the following suggestions if you are considering the purchase of a hearing aid.

Consider getting an ear examination

The Food and Drug Administration (FDA) recommends that you have your ears examined by a licensed physician. Ear examinations are universally recommended by the medical community to ensure there are no underlying diseases or medical problems causing the hearing loss. A hearing loss may be a symptom of another medical problem that needs a doctor's attention. Also, the cause and severity of a hearing loss vary widely from person to person. Be wary of any advertisements for hearing aids that play down the need for a medical examination and a hearing test. Dispensers or providers that encourage you to sign a waiver for a medical examination may be selling products that do not meet industry standards.

Get a hearing evaluation from a dispenser or an audiologist

Have your hearing tested to assess your ability to hear with and without a hearing aid. This test

will enable a dispenser or audiologist to select and fit a hearing aid to your individual needs. (The term "dispenser" refers to anyone selling hearing aids, whether the person is a hearing aid dealer or an audiologist.)

Check out the dispenser

Before you buy, check the reliability of local hearing aid dispensers with your local Better Business Bureau (BBB), consumer protection agency, or state attorney general. You also may want to verify the reliability of dispensers and physicians with their licensing boards in your state capital. Ask if there are any complaints on file, and how the company or professional has responded to the complaint.

Ask the dispenser or audiologist about a trial period

Many manufacturers, hearing specialists, and consumer groups recommend, and some state laws require, that consumers be given at least a 30-day trial period with only a small service fee (varying from five to 20 percent of the purchase price) if the consumer returns the product. In fact, manufacturers routinely make adjustments and permit hearing aid returns within 60 to 90 days at no charge to the dispenser. A trial period is strong protection for such an important purchase, so ask before you buy.

Remember, if you purchase a hearing aid from a door-to-door salesperson you have the right under the FTC's Door-to-Door Sales Rule to cancel within three business days of any sale for \$25 or more. The sale may take place in your home, or at a location that is not the seller's regular place of business.

If you are thinking of buying a hearing aid through the mail, consider the difficulty of getting the right hearing aid for your needs and a

proper fit. Although there is no federal law against the mail order sale of hearing aids, several states have banned hearing aid sales by mail. In states that do allow the sale of aids by mail, the transaction is subject to the FTC's Mail Order Rule. This rule requires companies to ship purchases made by mail when promised or give consumers the option to cancel their order for a refund.

Be aware of sales practices

Avoid being pressured into buying a hearing aid. As with any other medical decision, you should be given the opportunity to seek additional information or a second opinion. Sales personnel using high-pressure approaches demonstrate little concern for your well being.

Purchase Agreements

The hearing aid purchase agreement, or contract, should contain all terms of the transaction in writing, including an explanation of all verbal promises. In reviewing your agreement, remember to consider the following:

- Is there a written warranty?
- Is the warranty honored by the manufacturer or by the dispenser? (In some cases warranties by the manufacturer may not be recognized unless the hearing aid is purchased from a seller authorized by the manufacturer.)
- What services, if any, will be provided free of charge, and how long will they be provided?
- Will you receive a "loaner" if your hearing aid needs to be repaired?

(over)

- Do business with a dispenser who will clarify these details and put all verbal commitments into the written contract.

Federal Standards for Sales

The FTC is responsible for monitoring the business practices of hearing aid dispensers and vendors. Under the Federal Trade Commission Act, the FTC can take action against a company that misleads or deceives consumers. Such a company may use misleading sales and advertising practices — giving inaccurate information about hearing loss, performance of a hearing aid, refund policies, or warranty coverage. The Magnuson-Moss Warranty Act, which the FTC enforces, provides consumers with certain protections relating to warranties. This act requires a company offering a warranty to fully disclose all its terms and conditions.

The Food and Drug Administration (FDA) enforces regulations that deal specifically with the manufacture and sale of hearing aids, because these products are recognized as medical devices. FDA regulations have the force of federal law. According to the FDA, the following conditions must be met by all dispensers before selling a hearing aid:

- Dispensers must obtain a written statement from the patient signed by a licensed physician. It must be dated within the previous six months, state that the patient's ears have been medically evaluated, and state that the patient is cleared for fitting with a hearing aid.
- A patient, age 18 or older, can sign a waiver for a medical examination, but dispensers must advise the patient that waiving the examination is not in the patient's best health interest.

- Dispensers must avoid encouraging the patient to waive the medical evaluation requirement.
- Dispensers must advise patients who appear to have a hearing problem to consult promptly with a physician.
- The FDA regulations require that an instruction brochure be provided with the hearing aid that illustrates and describes its operation, use, and care. The brochure also must list sources for repair and maintenance and include a statement that the use of a hearing aid may be only part of a rehabilitative program.

State Standards for Sales

In addition to federal regulation, many states have laws that apply to the sale of hearing aids. Most states license hearing aid dispensers, and several states prohibit the sale of hearing aids through the mail. Purchasers also may be protected by implied warranties, created by state law. Your state Attorney General's Office can provide you with particular information about state laws that apply to the sale of hearing aids.

The state Attorney General's Office also will have information on whether hearing aid dispensers must be licensed or certified by the state. Some hearing professionals, such as physicians and audiologists, may be licensed by a state regulatory agency. These agencies may provide helpful information for individuals considering a hearing aid purchase.

Where to Complain

If you have questions or complaints concerning the sales practices of a hearing aid dispenser, contact your state Attorney General's Office,

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local consumer protection agency, the Better Business Bureau, and write: Correspondence Branch, Federal Trade Commission, Washington, D.C. 20580. Although the FTC usually does not resolve individual disputes, the agency may take action against a company if there is evidence of a pattern of deceptive or unfair practices.

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Medical Center
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Washington DC 20422

In Reply Refer To:

October 7, 1993

Senate Special Committee on Aging
Room SDG-31
U.S. Senate
Washington, DC 20510

Dear Committee Members:

My written statement on hearing aids and the older consumer is enclosed. Thank you for addressing this important issue on behalf of older Americans. I appreciate the opportunity to provide comments. Please contact me if I can be of further assistance. I can be reached at 202-745-8270.

Sincerely,

Lucille B. Beck

Lucille B. Beck, Ph.D., Associate Chief
Audiology and Speech Pathology Service (126)

Comments for the U. S. Senate Special Committee on Aging

Introduction

My name is Lucille Beck and I am the Associate Chief of the Audiology and Speech Pathology Service at the Department of Veterans Affairs (VA) Medical Center in Washington, D.C. I appreciate the opportunity to provide written comments regarding hearing aids and older Americans, and I commend you for making this important and complicated issue a priority in your committee's work. I believe that the existing marketplace is confusing for the consumer. Many consumers who could benefit from hearing aids do not use them, either because they are afraid to try hearing aids or they have had bad experiences in the marketplace. Since hearing loss is prevalent in one third of older Americans, they are disproportionately affected by this problem. Senior citizens comprise one half of all persons seeking help for hearing problems.

My comments are based on my experience and observations as an audiologist who has provided hearing aids and currently directs an audiology clinic which last year dispensed over 1000 hearing aids. Since the mid 1980s, I have been the Associate Coordinator of the VA National Hearing Aid Program and its Chief of Hearing Aid

Technical and Clinical Services for the VA nationwide. In addition, I hold faculty appointments at Gallaudet University and George Washington University as an associate professorial lecturer teaching graduate courses in hearing aids and amplification strategies. I have served as a advisor to local consumer groups and, for five years, as a member of the board of trustees for Self Help for Hard of Hearing People, Inc. (SHHH), a national hard of hearing consumer group. I am a consultant to the FDA Ear, Nose, and Throat panel and have served either as a panel member or consultant for ten years. I was elected president of the American Academy of Audiology, a professional audiology organization, and am currently serving my presidential term.

Effect of Advertising on Consumer Expectation

Reports from hearing aid users and potential users throughout the years have caused me to believe that there are many deceptive sales practices prevalent in the hearing aid marketplace. In recent years, certain manufactures have engaged in aggressive sales practices that clearly overstate the value of the circuitry. Consumer expectation is shaped by this type of advertising, causing some consumers to believe that hearing aids can restore normal hearing function and focus on the signal of interest by amplifying only that signal. This type of inappropriate promotion leads to dissatisfaction with the device and lack of motivation to learn to use the hearing aid properly.

The consumer will not be fully successful in a system where shopping around for product and price are required, since it assumes that all products are the same and that the consumer can make a determination of effectiveness from among hundreds of products. Depending on the nature and degree of hearing loss, the level of performance will be different. Consumers must be full informed of performance expectation and advertising must not mislead consumers. The recent actions of the FDA, warning manufacturers about deceptive advertising practices, along with its announcement of intent to require clinical data to substantiate claims, will ensure better protection for the consumer.

Technological Advances

Hearing aids are remarkable devices, and they continue to develop and refine as technological enhancements occur. They have changed dramatically since the implementation of the 1977 FDA regulations which govern the sale and manufacture of hearing aids today. At that time, hearing aids functioned more like general amplifiers. The nature of amplification, commonly referred to as electroacoustic characteristics, was similar for most hearing aids. Basically, hearing aids provided gain or amplification, which made the signal louder, with a simple frequency response, which amplified all of the various frequencies or pitches in a similar manner. It was not until the late 1970s that the idea of custom-in-

the-ear hearing aids, which were custom made to fit into the ear, and had custom-designed amplification, that is electroacoustic characteristics selected to compensate for hearing loss on an individual basis, became possible. Hearing aids were just beginning to offer the myriad of special functions available today.

Reference to the increasing sophistication in hearing aids was made by the FDA Commissioner in 1977. The Commissioner stated that hearing aid dispensers of the future must recognize their obligation to achieve greater competency in testing hearing in order to select and fit a hearing aid properly (42Fed Reg 31, [1977]). Hearing aids of today are technologically advanced, offer a wide range of acoustic and electronic variations, and provide an armamentarium of circuit options and programmable features for the user. Hearing aids still do not restore hearing function to normal, nor can they selectively recognize the speech signal and amplify only that signal. Hearing aids are however effective and beneficial, and when properly fitted, mitigate the effects of hearing loss for many people. The hearing aid of today offers many special features to compensate for loudness discomfort to certain sounds (i.e., abnormal loudness growth), a special difficulty often encountered by people with hearing impairment whereby even moderately loud sounds can be too loud. For the hearing aid to be properly fitted, it must have electroacoustic characteristics appropriate to compensate for the degree and configuration of hearing loss and the circuit options needed to make residual hearing function effective for communication.

Regardless of the type of hearing aid fitted, a program of rehabilitation instruction in hearing aid use and compensatory behaviors is required. In some cases, use of assistive technology for adverse listening situations and telephone communication is also necessary. Clearly, the hearing aid of today is far more sophisticated than the hearing aid available in the 1970s. It is essential that the potential hearing aid user receive an accurate and complete assessment of hearing function and a program of rehabilitation as part of any hearing aid provided today.

Credentials of Providers - Assuring Quality Care

In 1977, the profession of audiology was in its developmental stages as a provider of hearing aids, except in a few settings such as the VA (where audiologists have routinely dispensed hearing aids as part of audiological practice since the late 1950s). In fact, audiology was in its infancy as a recognized profession at that time.

The first licensing law in audiology was enacted in 1969 in Florida, and today approximately 43 states license audiologists to practice. Hearing aid selection, fitting, and dispensing, are part of the scope of practice for audiology and routinely taught in audiology graduate programs and as part of the clinical practicum experience for audiology training. This is recognized as part of the audiology license in 13 states who do not require a separate license to dispense aids. States which have passed licensing laws in recent years have routinely included hearing aid dispensing as part of the audiology license. States which enacted audiology licensing laws years ago did not include dispensing of hearing aids. In fact, the American Speech-Language-Hearing Association, the national accrediting professional association which awards the certificate of clinical competence in audiology, (a self-imposed alternate until there is full fledged licensing in all 50 states) did not consider hearing aid dispensing to be part of the scope of practice until 1978.

The FDA Regulations - Revisited

During the development of the FDA 1977 regulations, inclusion of an audiologic assessment as a precursor to the fitting of a hearing aid was advocated and subsequently required for children only. Today, audiologists routinely combine assessment with fitting in a variety of practice settings including hospitals, speech and hearing centers, ENT physicians' offices, HMO settings, private practice, and school systems as well as the traditional university settings where audiologists teach and conduct research.

The 1977 regulations also required a medical evaluation as a precursor to the sale of a hearing aid. At that time, hearing loss was regarded primarily as a symptom of disease, and it was felt that the safety of the public would be best served by a requirement for medical evaluation. It should be noted that the purpose of the evaluation was to ensure that there was no medical contraindication to hearing aid use. The medical evaluation was not intended to be an indicator of potential success with a hearing aid or a guarantee of consumer protection. Since responsibility for fitting and sale of a hearing aid, newly regarded as a medical device, was relegated to hearing aid dealers, individuals with no formal training in hearing, the medical clearance requirement was meant to ensure that the use of a hearing aid was not substituted for proper medical intervention. This safeguard considered sufficient to ensure that the masking of a serious medical condition would not occur as a result of purchasing a hearing aid. Apparently, hearing aids were considered to be relatively simplistic amplifying devices which could be appropriately fitted without any formal education and training. Audiologic assessment, considered necessary for children, was not deemed necessary for adults, who it was assumed through a process of trial and error could make informed decisions about hearing aid use.

Since the time of those regulations, it is now understood that only 5 to 10% of all hearing loss is medically or surgically treatable. Hearing loss does occur separately from ear disease. Two of the most well-known causes of hearing loss are noise-induced hearing loss, caused by exposure to loud noise, and presbycusis, hearing loss due to aging. The presence of hearing loss results in a sensory deficit, a condition distinct from the existence of a disease requiring medical treatment. There are similar analogies in the vision system where it is well understood and generally expected that some loss of vision will occur as part of the aging process. Qualified professionals, such as optometrists and ophthalmologists, measure visual acuity and prescribe corrective lenses.

The medical evaluation does not provide information about potential benefit with hearing aids. It is the diagnostic audiologic evaluation which determines the degree and nature of hearing loss, the status of middle ear function, speech perception ability, and the need for site of lesion testing. Important, as well, is the complex interrelationship between the amount of organic hearing impairment and the individual's complex set of communication needs. Individuals who provide comprehensive audiology assessment, the fitting of today's technologically sophisticated hearing aid, and associated hearing care counseling and aural rehabilitation must receive formal education and supervised clinical practicum to become qualified to provide these critical healthcare services to consumers. In addition, it is essential that hearing tests be done under exacting conditions using sound-treated rooms with carefully calibrated equipment. These requirements and the necessary standards of care are well-defined for medical-legal examinations and pre-surgical examinations. The same exacting standard of care by a qualified professional is a necessary precursor to a hearing aid evaluation.

The VA Hearing Aid Program - Audiologists as Providers

The Department of Veterans Affairs has provided hearing aids and aural rehabilitation to its veterans with hearing loss since after World War II. In fact, the profession of audiology began as part of the provision of rehabilitation services to veterans with hearing loss in Army hospitals. Since the inception of its program during the 1950s, the VA has provided hearing aids as part of a comprehensive program of audiology care. Today, the VA has approximately 400 audiologists in its Audiology and Speech Pathology Services who dispense hearing aids in about 100 medical centers and outpatient clinics around the country. In fiscal year 1993, the VA dispensed approximately 70,000 hearing aids to veterans with continuing eligibility.

The VA program is characterized by two key elements which form the benchmarks for high quality care. One element is a comprehensive electroacoustic evaluation program which evaluates hearing aids to determine the nature and quality of their electroacoustic characteristics. The second key element is the services of the professional audiology staff, that is, the comprehensive audiologic evaluation, hearing aid and earmold selection, the hearing aid evaluation, the dispensing of the instrument, and appropriate follow-up care.

The VA has developed a model electroacoustic testing program for selection quality hearing aids at a reasonable cost. The testing program, conducted by the National Institute of Standards and Technology, identifies high quality hearing aids that meet the hearing loss needs of the veteran population. The needs of the pediatric population, for example, would not necessarily be reflected in VA testing. The results of the testing program are made public through a report called the Handbook of Hearing Aid Measurement. The 1992 report was provided previously to the committee. The report is very technical and is useful to audiologists and engineers. A non-technical version is available for consumers. Because it is well known that the VA has a comprehensive hearing aid test program, we are often asked by consumers and consumer groups to provide advice. The VA has always been reluctant to name the best hearing aid for two reasons. The first is that there are many good models which the VA does not test and, as mentioned previously, the testing is designed to identify aids that particularly meet the needs of the veteran population. The second reason, and the important one regarding professional services, is that a high quality hearing aid (i.e., the hearing aid that scores number one in our program), is only good when it is appropriately fitted. In other words, the hearing aid must have a set of electroacoustic characteristics which compensates appropriately for the individual's hearing loss.

The VA testing program provides the framework which, when coupled with the services provided by the audiologist, results in good hearing health care. The efforts of the VA are directed towards the provision of the proper tools for audiologists, as well as for the hearing impaired. The key component then becomes the services of the professional audiology staff, the comprehensive audiologic evaluation including the otoscopic examination, hearing aid and earmold selection, the hearing aid evaluation, the dispensing of the instrument and the appropriate follow-up care.

Dispensing of hearing aids is provided as part of a comprehensive program of care. The first requirement is the comprehensive audiologic assessment. Veterans eligible for hearing aids are given high priority for this first appointment. Veterans are referred directly to the Audiology Clinic for this exam and are not routinely scheduled for a medical or an Ear, Nose, and Throat exam unless the audiologist determines that medical management is necessary (VHA

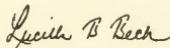
directive 10-92-009, January 17, 1992). By virtue of their graduate education and practicum training, audiologists are well-qualified to recognize when patients with hearing loss should be referred for medical consultation. Graduate coursework includes courses in hearing disorders and ear disease. Since less than 10% of hearing loss is medically and/or surgically treatable, and since many of the tests that audiologists perform and interpret are routinely used to diagnose disease, this procedure ensures the proper screening for potential medical intervention.

Subsequent appointments include the fitting of the hearing aid, instruction in how to use the hearing aid, a program of rehabilitation, counseling, and practice including training in listening skills, coping strategies, and meeting special communication needs. There are well defined standards of care for the fitting of the hearing aid. In 1990, the VA co-sponsored the Vanderbilt Conference, a state of the art conference on hearing aids. The published conference proceedings included a report entitled "Recommended Components of a Hearing Aid Selection Procedure for Adults "(copy provided). VA has subsequently adopted that standard of care for the selection, fitting, and dispensing of hearing aids by audiologists in the VA. In addition, the VA has delineated criteria for the provision of hearing aid services and selection of required audiometric sound booths and equipment (VHA directive 10-92-094, September 14, 1992).

VA Advice To The Consumer

Regarding hearing aids and associated services, our advice to veterans and the general public is to seek the services of a qualified professional, an audiologist. We do not generally advise consumers by brand but suggest that consumers see professionals who provide high quality products and provide excellent services. The professional services that accompany the product, and most importantly, the professional judgment used to select the right product to meet the individual's needs (hearing loss, occupational, physical, social, and economic) are, in my opinion, the benchmarks for success with a hearing aid. I believe that a diagnostic audiology assessment, correctly performed and interpreted by an audiologist is the foundation for service provision and benefit from a hearing aid. Audiologists are qualified by virtue of formal education and supervised clinical training as described by the recognized education models in health care training today. The hearing aid of today has moved far beyond the days of a provider who has no formal qualifications.

Thank you for the opportunity to comment. If I can be of further assistance, please contact me.



Lucille B. Beck, Ph.D.

APPENDIX II

Vanderbilt/VA Hearing Aid Conference

1990 Consensus Statement

Recommended Components of a Hearing Aid Selection Procedure for Adults

Following the conference, Dr. Allen E. Boysen, Director of Central Office, Audiology and Speech Pathology Service, Department of Veterans Affairs (VA), charged a small working group from the conference faculty with the development of a consensus statement on hearing aid selection procedures for adults. The members of the committee who prepared the following statement are: David B. Hawkins, Chair, University of South Carolina, Columbia, South Carolina; Lucille B. Beck, Department of Veterans Affairs, Washington, D.C.; Gene W. Bratt, Veterans Administration Medical Center, Nashville, Tennessee; David A. Fabry, Mayo Clinic, Rochester, Minnesota; H. Gustav Mueller, Letterman Army Medical Center, San Francisco, California; Patricia G. Stelmachowicz, Boys Town National Research Hospital, Omaha, Nebraska.

I. Introduction

Significant changes have occurred in hearing aid circuitry, the measurement of hearing aid performance, and hearing aid selection procedures in the ten years since the first Vanderbilt/VA Hearing Aid Report. Although much of this new technology has been integrated into the clinical setting, there still is no universally accepted protocol for selecting an appropriate hearing aid for a given individual. Certain aspects of the selection procedure, however, can be agreed upon by most individuals familiar with both the research literature and the constraints of clinical practice. The purpose of this consensus statement is to outline the recommended components of a hearing aid selection procedure which meets the following

five criteria: (1) it is defensible based upon current research literature, (2) the responsibility for decision making rests with the audiologist, (3) the goals for hearing aid performance are clearly stated, (4) these amplification goals are measured and verified, and (5) counseling and follow-up procedures are viewed as essential.¹

II. Hearing Aid Candidacy

The first decision that must be addressed is whether a person is a candidate for hearing aids. It is inappropriate to determine hearing aid candidacy by referring only to hearing sensitivity as represented by thresholds for pure-tone signals or scores on word recognition tests. Anyone who describes hearing difficulties in communicative situations should be considered a potential candidate for hearing aids or other assistive devices. Unless clear contraindications exist, binaural hearing aids should be considered the preferred fitting for the prospective hearing aid user.

III. Determination of Initial Electroacoustic Characteristics

A. Selection of SSPL90

Some accepted type of supra-threshold judgment (e.g. loudness discomfort levels, uncomfortable loudness levels, or highest comfortable levels) should be used to determine an appropriate maximum output of the hearing aid. If the person is unable to perform such judgments, a data-based predic-

¹This procedure is not intended to address issues related to selection of hearing aids for young children.

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- tion method should be used to determine the SSPL90 setting. For instance, Cox (1985) has suggested that SSPL90 could be determined by the equation $100 + \frac{1}{4} \text{ HL}$. Other recommendations for selecting SSPL90 based upon pure-tone thresholds can be found in Cox (1988), Seewald and Ross (1988), and Skinner (1988).
- B. Selection of Gain/Frequency Response
- Two-cm³ coupler gain should be determined which will yield desired real-ear performance as specified by a published gain/frequency response selection procedure (e.g. Berger, Hagberg, and Rane 1988; Byrne and Dillon 1986; Cox 1988; Libby 1986; McCandless and Lyregaard 1983; Schwartz, Lyregaard, and Lundh 1988; Seewald, Ross, and Stelmachowicz 1987; Skinner 1988). Many procedures provide corrections from desired real-ear gain to 2-cm³ coupler gain for the average person. The best approach would be to obtain corrections on an individual basis rather than relying upon average values incorporated into the prescription procedure. An example of such a correction procedure can be found in Punch, Chi, and Patterson (1990). The particular corrections will depend upon the style of hearing aid used. (Use of certain programmable or newer hearing aid circuitry may obviate the need for some 2-cm³ coupler real-ear conversions.)
- C. Selection of Special Circuit Options
- Decisions concerning output limitation options, special circuitry needs, etc. should be made at this point.
- IV. Determination of Important Hearing Aid Features
- Considerations of a variety of important hearing aid features must be incorporated into the decision making process. A needs assessment should be determined for a number of options or features, such as style of hearing aid, telecoil, direct audio input, raised volume control wheels, and directional microphone.
- V. Selection of Hearing Aid(s) that Meet Desired Electroacoustic Characteristics
- For behind-the-ear (BTE) hearing aids, the audiologist must select a hearing aid with the appropriate electroacoustic characteristics and options from available specification sheets. For in-the-ear (ITE) hearing aids, the audiologist should order the instrument by either (a) specifying the desired SSPL90 and full-on 2-cm³ coupler gain (assuming a reserve gain of 10-15 dB), or (b) selecting an appropriate specific circuit designation described by the manufacturer.
- VI. Verification of Selected or Ordered Electroacoustic Characteristics
- Upon receipt of the hearing aid and prior to delivery to the hearing aid user, electroacoustic measurements performed according to ANSI standards (S3.22 1987) should be completed to verify that the hearing aid functions according to the manufacturer's specifications. Additionally, in the case of an ITE hearing aid, the 2-cm³ coupler gain and SSPL90 should be examined to determine if an appropriate circuit was delivered from the manufacturer.
- VII. Performance Assessment of Hearing Aid Characteristics on the User
- A. Setting and Verification of SSPL90
- The SSPL90 should be set to an appropriate level based upon earlier measurements. Verification of the chosen SSPL90 setting for prevention of loudness discomfort and overamplification should be performed for each ear. This determination can be accomplished through a variety of methods, such as Real Ear Saturation Response (RESR), or presentation of controlled signals or intense environmental sounds to saturate the hearing aid.
- B. Verification of Desired Real-Ear Gain/Frequency Response
- The hearing aid should be adjusted to approximate as closely as possible the previously determined target values for each ear. Verification methods may include functional gain, aided sound-field thresholds, Real Ear Aided Response (REAR), or Real Ear Insertion Response (REIR). A determination that adequate reserve gain is available at the chosen use volume control position should be made as well.
- C. Other Assessments
- Some type of assessment, formal or informal, should be made of special fea-

tures of the hearing aid, such as a determination of whether adequate telecoil strength is available for the use of the telephone. The person's subjective reactions to amplified sound should be included in the evaluation. An assessment of the person's ability to understand amplified speech should be made. A number of different approaches, such as speech recognition scores, speech intelligibility ratings, or informal subjective responses, can be used for this purpose.

VIII. Counseling and Follow-up Procedures

Regardless of the selection strategy employed, proper counseling during the fitting and orientation and careful follow-up procedures are necessary if hearing aids are to be used successfully. During the initial stages of adjustment to amplification, electroacoustic characteristics may need to be altered based upon reactions and experiences of the hearing aid user. In addition, questions may arise that were not considered at earlier sessions, and misunderstandings about information provided earlier and expectations may need to be clarified. Finally, other concerns about communicative strategies, remaining difficulties, and use of other devices may need to be explored. Without adequate counseling and follow-up, a well-selected hearing aid can be used improperly, inadequately, or not at all.

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Department of Veterans Affairs
 Veterans Health Administration
 Washington, DC 20420

VHA DIRECTIVE 10-92-094

September 14, 1992

TO: Regional Directors; Directors, VA Medical Center Activities, Domiciliary, Outpatient Clinics, Regional Offices with Outpatient Clinics (00/126)

SUBJ: Criteria for Independent Status as a Hearing Aid Dispensing Program

1. PURPOSE: The purpose of this VHA (Veterans Health Administration) directive is to provide minimum criteria which ASPSs (Audiology and Speech Pathology Services) must meet to qualify for status as a VAIHAP (Department of Veterans Affairs Independent Hearing Aid Dispensing Program). This directive will be incorporated into M-2, part XVIII, chapter 3.

2. BACKGROUND

a. There has been a large increase in the number of hearing aids issued to veterans in the last 10 years. Currently there are 57 extended ASPSs, clinics authorized to conduct transactions with the VADDC (VA Denver Distribution Center) for stock hearing aid inventory and for ordering custom ITE (in-the-ear) hearing aids. During these 10 years, many basic ASPS programs became satellites to the extended programs in an effort to provide more convenient services to non-ambulatory veterans. The extended ASPSs maintain a limited inventory of stock aids at the satellite locations to minimize inventory costs and to exercise some administrative controls over paperwork.

b. Several factors now make the extended/satellite clinic concept unnecessary:

- (1) Increased demand for hearing aid related services has resulted in appointment backlogs at both extended and satellite clinics.
- (2) Custom ITE aids currently account for over 80 percent of all hearing aids issued. Stock hearing aid inventories no longer represent the cost outlay required several years ago.
- (3) Decentralization of C & P (Compensation and Pension) examinations leaves only hearing aids as a major audiology service not provided by all ASPSs with an audiologist.

(4) The ROES (Remote Order/Entry System), a VA DHCP (Decentralized Hospital Computer Program) software program for electronic ordering of hearing aids through the VADDC, is being implemented in ASPSs during FY 1992 with the assistance of IRMS (Information Resources Management Services).

3. POLICY

a. It is VHA policy to ensure that all VA ASPSs providing hearing aid services independently do so in a timely manner and according to VA standards. The following criteria are minimum standards for establishing and maintaining services required as a VAIHAP:

THIS VHA DIRECTIVE WILL EXPIRE SEPTEMBER 14, 1993

(1) Staff support

(a) A minimum of 1.5 FTEE (Full-time Employee Equivalent) audiologists, not counting the service chief if an audiologist. If the service chief is a speech pathologist, a minimum of 2.0 FTEE audiologists is required.

(b) A minimum of 1.0 FTEE secretary.

(c) A minimum of 0.5 FTEE clerk or audiometric (health) technician if the ASPS is providing HAEs (hearing aid evaluations) for another VA medical center or satellite clinic.

(2) Equipment

(a) All instrumentation and materials required to accomplish the standard VA test battery used for Audiology C & P Examinations.

(b) A sound-isolated test suite with two rooms. The room for examination of the patient must have double walls and be of sufficient size to accomplish sound-field measures.

(c) A real ear probe tube measurement system for fitting hearing aids.

(d) A hearing aid test box for electroacoustic analysis of hearing aids.

(e) Tools, materials, and spare parts for maintenance, minor repair, and adjustment of hearing aids and earmolds. These include a high speed bench lathe or dental drill for grinding and buffing custom ITE aids and earmolds.

(3) Space

(a) The Audiology clinic must have a separate room of at least 120 square feet for electroacoustic analysis of hearing aids and a large workbench for equipment used for in-house maintenance and adjustments.

(b) The Audiology clinic must have a separate room of sufficient size to accommodate a group of patients, family members, and an audiologist for the purpose of providing auditory rehabilitation.

(c) The Audiology clinic must have the space to house the inventory of stock aids and a method to ensure security of those instruments. A locking cabinet is satisfactory.

(4) ENT (Ear, Nose, Throat) services: An ENT examination is not required prior to providing a hearing aid evaluation. Patients with otoscopic or audiologic evidence of ear disease must be referred for a complete otologic evaluation. Therefore, ENT consultation must be available. Clinical privileges for audiologists in the removal of cerumen (with immediate access to the proper equipment in the audiology clinic area) is desirable.

(5) Audiologists are the professionals who dispense hearing aids. To ensure high quality professional services, audiologists are expected to follow VA minimum standards for hearing aid evaluation as outlined in the VA/Vanderbilt Hearing Aid Report II. Of particular importance is utilization of electroacoustic systems for hearing aid measurement and fitting; making hearing aid and earmold modifications and minor repairs to both custom ITE and behind-the-ear hearing aids; and utilization of real ear probe tube systems in hearing aid selection and evaluation. Training through continuing education is recommended to ensure thorough knowledge and skill with these rapidly advancing technologies.

b. Justification for a VAIHAP: Designation of additional clinics as independent hearing aid dispensing programs may have a negative impact on workload and resources at both new and existing independent clinics. In order to avoid this undesirable outcome, the following criteria will be used to determine the need for additional independent dispensing programs.

(1) The VA Audiology clinic must be located at least 50 miles from the nearest existing independent dispensing program. Exceptions to this rule are areas where there is a population concentration and/or public transportation is inadequate.

(2) The workload from the audiology clinic's catchment area is sufficient to warrant independent status. If the proposed VAIHAP is an addition to the current number of programs, the desired results of its implementation should be:

- (a) Reduction in backlog at an existing VAIHAP;
- (b) No adverse impact on the workload at an existing program;
- (c) No backlog created at the new independent clinic.

c. An ASPS that meets the criteria for a VAIHAP must be a separate service in a VA medical center since this status verifies the concept of independent hearing health care professionals in an independent clinic.

4. ACTION

a. All ASPSs, including extended ASPSs, must apply for independent status as a hearing aid dispensing clinic in order to begin or continue dispensing hearing aids. The application form is attached to this directive.

b. A letter of commitment is required from a VA medical center's Director indicating the station's support for the priority of hearing health care and timeliness of hearing aid delivery in VHA Directive 10-92-009, the requirements for minimum space, staff, equipment, and ENT support, and a sufficient operating budget for supplies.

c. Applications will be reviewed by a committee of VA audiologists appointed by the Director, ASPS and the Coordinators, VANHAP (VA National Hearing Aid Program). This committee will make recommendations to the Director and the Coordinators regarding a clinic's status.

d. If the committee does not recommend independent status for an additional clinic, the applying clinic may continue as a satellite to an independent program until such time that it meets the established criteria in this directive. A plan for acquisition of resources necessary to achieve independent status will be forwarded to the Director, ASPS and the Coordinators, VANHAP.

e. Extended ASPSs that do not meet all the criteria will have the opportunity to upgrade the quality of their clinics and reapply for independent status.

f. In general, the workload for any VAIHAP will come from the catchment area of its medical center. In cases where there are unusual geographic or population considerations, the division of workload between a new and an existing VAIHAP must be mutually satisfactory to both programs.

g. Sudden increases or decreases in workloads must be avoided. A plan must be developed for gradual assumption by the new VAIHAP of workload previously directed to an existing VAIHAP. This plan must be mutually satisfactory to both programs.

h. Any change in a VAIHAP's ability to meet the criteria for independent status that continues beyond 90 days must be reported to the Coordinators, VANHAP.

i. A quarterly review of hearing aid budget target allocations is required for all VAIHAPs. Any deviation exceeding plus or minus 10 percent of the budget for that quarter must be reported to the Coordinators, VANHAP along with an explanation of the deviation and a projection for the next quarter's budget. This report may be transmitted via the IDCU network.

j. Send the completed form to the following address:

Coordinators

VA National Hearing Aid Program Audiology & Speech Pathology Service (126)
VA Medical Center
50 Irving Street N.W.
Washington, DC 20422

k. The form will be forwarded to the reviewing committee for a decision regarding the status of your program. You will be notified as soon as possible.

5. REFERENCES

- a. The Vanderbilt Hearing Aid Report II, Edited by Studebaker, G., Bess, F., and Beck, L., in cooperation with the Department of Veterans Affairs, 1991, pp. 321-323.
 - b. VHA Directive 10-92-009, "Guidelines for Delivery of Hearing Aids".
6. **FOLLOW-UP RESPONSIBILITY:** Director, Audiology and Speech Pathology Service (117E).

7. **RESCSSIONS:** None. This VHA directive will expire September 14, 1993.



JAMES W. HOLINGER, JR., M.D.
Chief Medical Director

Attachment

DISTRIBUTION: CO: E-mailed 9/15/92
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ATTACHMENT A

**APPLICATION FOR
VA INDEPENDENT HEARING AID DISPENSING PROGRAM**

Medical Center location: _____ Number: _____

Contact person: _____ FTS Number: _____

1. Staffing Information

- | | | | |
|----------------------|------|----|----|
| a. Audiologist(s): | FTEE | FT | PT |
| b. Secretary: | FTEE | FT | PT |
| c. Clerical staff: | FTEE | FT | PT |
| d. Audiometric tech: | FTEE | FT | PT |
| e. Other: | FTEE | FT | PT |

2. Equipment Information

a. Number of sound-isolated test suites with double walls for sound-field testing: _____

b. Instrumentation and materials required to accomplish the standard test battery used for audiology C & P (Compensation and Pension) examinations: Yes _____ No _____

If no, list the equipment and/or materials missing:

c. Real ear probe tube measurement system: Yes _____ No _____

If yes, list make and model of system(s):

d. Hearing aid test box: Yes _____ No _____

If yes, list make and model of system(s):

e. Tools and accessories for earmold and ITE (in-the-ear) modifications and minor repairs:

- (1) Drill: Dremel _____
- (2) Grinder/polisher_____
- (3) Retubing instrument_____
- (4) Spare parts (e.g., battery doors, control covers, hooks, etc.) Yes _____ No _____
- (5) List any additional items:

f. ADP (Automated Data Processing) equipment

- (1) IRMS (Information Resources Management Services) terminal(s) or ASPS (Audiology and Speech pathology Services) PC(s) (Personal Computer) with access to the DHCP(Decentralized Hospital Computer Program) in your immediate clinic area: Yes _____ # _____; No _____
- (2) DHCP printer(s) in your immediate clinic area: Yes _____ # _____ No _____
"Slave printer capable": Yes _____ # _____ No _____

3. Program Support

a. Your medical center Director supports your application for independent status as a hearing aid dispensing clinic. In doing so, they support the priority of hearing health care and timeliness of hearing aid delivery in Directive 10-92-009, the requirements for minimum staff and equipment, and a sufficient operating budget. Yes _____ No _____

b. If yes, attach a letter of commitment from your Director.

4. Space

a. Approximate size of your clinic _____ sq.ft.

b. Number of rooms other than test booths _____

c. Is there a room of at least 120 sq. ft. to accommodate a workbench and the equipment required for hearing aid and earmold repair or modification? Yes _____ No _____

d. Is there a room of sufficient size to accommodate a group of patients and family for auditory rehabilitation? Yes _____ No _____

e. Is the required space available to store and secure a stock hearing aid inventory? Yes _____ No _____

If yes, describe the security of this space:

5. ENT Services

a. Is there an ENT clinic in your medical center? Yes _____ No _____

b. Are the services of an otolaryngologist available on a routine basis? Yes _____ No _____

List days and times:

c. Are the staff audiologists privileged in non-impacted cerumen removal? Yes _____ No _____

6. Professional Knowledge/Experience

a. Staff audiologists have had training in the use of electroacoustic systems for hearing aid measurement and fitting? Yes _____ No _____

b. Staff audiologists have had training in making hearing aid and earmold modifications and minor repairs to both custom ITE and behind-the-ear hearing aids. Yes _____ No _____

c. Staff audiologists have had experience with real ear probe tube systems in hearing aid selection and evaluation. Yes _____ No _____

If yes, list the audiologists and the number of years of experience in this area:

If yes, provide documentation of academic course work, continuing education, supervised practica, etc.

7. Justification for status as a VA (Department of Veterans Affairs) VAIHAP (Independent Hearing Aid Dispensing Program)

a. The nearest existing VAIHAP is _____ miles away.

b. During the past 12 months, what is the average number of hearing aid evaluations done from your catchment area per month _____

c. If your clinic does hearing aid evaluations for patients from other VAMC catchment areas, list the average number done per month for each.

VAMC _____	Average number HAEs _____
VAMC _____	Average number HAEs _____
VAMC _____	Average number HAEs _____

d. Rate the availability and ease of use of public transportation from your catchment area to your medical center:

Excellent ____ Good ____ Fair ____ Poor ____

8. Other: Note any other information which you believe is important regarding your clinic's capability of performing as a VAIHAP:

CIRCULAR 10-89-103

September 25, 1989

Department of Veterans Affairs
Veterans Health Services and
Research Administration
Washington, DC 20420

TO: Regional Directors; Medical District Directors;
Directors, VA Medical Center Activities;
Domiciliary, outpatient Clinics, and Regional
Offices with outpatient Clinics

SUBJ: Standard Procedures for Audiology C&P (Compensation
and Pension) Examinations

1. PURPOSE: The purpose of this VHS&RA (Veterans Health Services and Research Administration) Circular is to establish policy on equipment, test materials, and standard procedures required for Audiology C&P examinations. This circular is a new issue and will be incorporated into M-2, part XVIII, chapter 3.

2. POLICY:

a. Disability awards are contingent upon the results of C&P examinations for hearing loss known as ASE (Assessment of Social Efficiency). Therefore, it is the responsibility of the audiologist to obtain accurate measures of the current organic impairment. Identification and, more importantly, resolution of non-organic hearing loss are required. The medical-legal importance of obtaining reliable and valid test results cannot be overemphasized since the financial impact on the government could be significant over a period of time.

b. To ensure that Audiology C&P examinations are conducted uniformly by audiologists at all VA medical centers and outpatient clinics, and by non-VA, fee-basis audiologists, standards of practice regarding equipment, test materials, and procedures are specified in this circular.

3. ACTION:

a. General Requirements

(1) The audiological C&P examination shall include the following: (a) air-conduction and bone-conduction thresholds, (b) SRT (speech-recognition thresholds), (c) word-recognition performance, and (d) acoustic immittance testing. One set of results for each of these tests should be reported on VA Form 10-2364, ("Audiological Evaluation").

THIS CIRCULAR WILL EXPIRE SEPTEMBER 25, 1990.

(2) VA Form 10-2464, ("Summary Report of Examination for Organic Hearing Loss"), should be completed by the responsible Chief, Audiology and Speech Pathology Service (ASPS), or a designated audiologist and forwarded with VA Form 10-2364 to the referring C&P (Medical Benefits) office for transmittal to the appropriate VA Regional Office Adjudication Service. The following standardized procedures and testing methods are required to ensure the accuracy of test results for rating purposes. These standard procedures are minimal requirements and do not prevent the audiologist from utilizing additional methods to verify that valid results have been obtained.

b. Equipment and Test Materials

(1) Calibration

(a) Daily. A detailed listening check should be performed daily and a log maintained. The listening check must include a check of the pure-tone circuit via earphones and the bone vibrator and a check of the speech circuit via earphones.

(b) Semi-annual. An electroacoustic calibration of all audiometers and acoustic-immittance devices must include 1 accuracy of output levels, frequency, and rise/decay times of pure tones; 2 attenuator linearity; 3 checks of harmonic distortion, signal-to-noise-ratio, and shock hazard; and 4 other measures in accordance with the American National Standard Institute Specification for Audiometers (ANSI S3.6-1969, R1973) and Specifications for Instruments to Measure Aural Acoustic Impedance and Admittance (Aural Acoustic Immittance) (ANSI S3.39-1987). Calibration records must be maintained.

(2) Test Materials. The materials used for speech-recognition thresholds (spondaic words) and for word-recognition performance (Maryland CNC Test, Lists 1, 3, 6, 7, 9, and 10) must be VA-approved recordings. Speech materials recorded on audio tape (cassette or reel-to-reel) must be replaced every 6 months, whereas speech materials recorded on compact disc need only be replaced when damaged.

c. Otologic Evaluation. Patients with no evidence of middle-ear disease may have an otoscopic examination by a staff audiologist or physician to determine that the ear canal is patent and free of debris and that the eardrum is intact. The results of this examination should be reported on a Standard Form 513 (medical consultation). Patients with otoscopic or audiologic evidence of external or middle-ear disease must have an otologic evaluation performed by a staff or resident otolaryngologist (see Section 3.11 of the "Physicians Guide for Disability Evaluation Examinations," March, 1985).

d. Test Procedures

In no instance should stimuli be presented above 105-dB HL for pure-tone tests and above 100-dB HL for speech tests. Appropriate masking levels should be used for all threshold and supra-threshold testing; effective masking levels must be reported.

(1) Case History. A VA Form 10-1162 (case history) should be conducted prior to the audiological evaluation. For veterans claiming service connection for tinnitus on VA Form 10-2507, the following information must be obtained and recorded under the "comments" section on VA Form 10-2364 and under remarks on VA Form 10-2464:

(a) The date and circumstance (e.g., head injury, acoustic trauma) describing the onset of tinnitus.

(b) Unilateral versus bilateral and constant versus periodic. If the tinnitus is periodic, then include the frequency of occurrence.

(c) The severity and effect of the tinnitus on daily living.

(d) The veteran's subjective evaluation of the loudness and pitch of the tinnitus.

(2) Otoscopic Examination. Even if this examination has been performed by a physician, an otoscopic examination must also be performed by the audiologist to check for occlusion of the ear canal, infection, and the possibility of ear-canal collapse prior to the audiological evaluation.

(3) SRT (Speech-Recognition Threshold).

(a) The SRT is the first test administered in a C&P examination. A VA approved recording of the 36 CID spondaic words or carefully monitored live voice is used to establish the SRT using an ascending technique. Familiarization with the spondaic words is accomplished by having the patient read aloud the list of 36 words. Patients unable to read are familiarized by repeating the 36 spondaic words presented by the audiologist face-to-face. Patients are encouraged to guess at the words as soon as they are able to detect any part.

(b) The starting level for the test procedure is established by presenting one spondaic word at 0-dB HL and increasing the level in 10-dB increments until the patient correctly repeats one word. The level is decreased 10 dB and spondaic words are presented in an ascending manner at each 2-dB or 5-dB increment. The SRT is the lowest level at which 50 percent of the stimulus words presented are repeated correctly. Fifty percent means that a minimum of four out of eight words taken from a randomized list of the 36 standardized CID spondaic words VA Form 10-7140, ("Spondee Lists") have been correctly recognized. It is essential that the sample of stimulus words not be restricted in such a way that a biased score is obtained because only very easy or very hard stimulus words are pre-selected and presented as test items.

(c) If the patient does not respond at the maximum level of 100-dB HL, 100+ should be recorded on Form 10-2364.

(4) Pure-tone Thresholds.

(a) Pure-tone, air-conduction thresholds are obtained at 250, 500, 1000, 2000, 3000, 4000, and 8000Hz. If there is a ≥ 20 -dB difference in thresholds between 1000 and 2000 Hz or between 4000 and 8000Hz, then thresholds must be obtained at 1500 or 6000Hz, respectively. Pure-tone, bone-conduction thresholds are obtained at 250, 500, 1000, 2000, 3000, and 4000Hz. Bone-conduction thresholds need not be obtained at frequencies where the pure-tone, air-conduction thresholds are 15 dB or better. Appropriate masking levels to establish air-conduction thresholds should be used whenever there is a ≥ 40 -dB difference between air-conduction thresholds in the test ear and bone-conduction thresholds of the non-test ear and to establish bone-conduction thresholds whenever there is a ≥ 15 -dB difference between air- and bone-conduction thresholds in the test ear.

(b) The maximum contralateral masking level used to verify threshold should be recorded on VA Form 10-2364. If an appropriate masking level cannot be used because of either equipment limits or overmasking in the non-test ear, then the maximum masking level is recorded with a "+" after the number (e.g., 90+). This indicates that the pure-tone threshold reported was obtained at the recorded masking level and that the pure-tone threshold might be different if more masking could have been used.

(c) A modified Hughson-Westlake procedure (Carhart & Jerger, 1959; ASHA, 1978) should be used to establish air- and bone-conduction thresholds. However, familiarization with the test tone should be avoided to minimize the possibility of eliciting suprathreshold responses. An ascending threshold search is begun using pulsed tones starting from an inaudible level with each subsequent presentation level increased in 10-dB steps until a response is obtained. The tone is decreased by 10 dB and then increased in 5-dB steps until a response occurs. The tone is again decreased by 10 dB to begin another ascending threshold search. Threshold is defined as the lowest level at which responses occur in at least half of the ascending trials with a minimum of three responses required at a given level.

(d) Failure to respond should be indicated with a "+" after the maximum allowable limit (i.e., 105+).

(e) The two-frequency average is always based on the two better thresholds at the frequencies 500, 1000, and 2000 Hz. The three-frequency average is based on the frequencies 500, 1000, and 2000 Hz. The four-frequency average is based on the frequencies 1000, 2000, 3000, and 4000 Hz.

(f) "Hearing within normal limits" for adjudication purposes is defined as follows:

All thresholds for the frequencies 500, 1000, 2000, 3000, and 4000 Hz must be less than 40 dBHL; the thresholds for three of these frequencies must be 25 dBHL or less; and maximum speech recognition scores must be 94 percent or better.

In order to standardize terminology describing severity of loss for puretone air-conduction stimuli, the following categories will be used:

HTL in dB	<u>Descriptive Terms</u>
-10-25	Normal Limits
26-40	Mild Hearing Loss
41-55	Moderate Hearing Loss
56-70	Moderately Severe Hearing Loss
71-90	Severe Hearing Loss
91+	Profound Hearing Loss

(5) Word-Recognition Performance.

(a) A VA approved recording of the Maryland CNC word-recognition materials (Causey et al. 1983, 1984) is used to measure maximum word-recognition performance on a 50-word list. Live voice presentation is not acceptable.

(b) Normal word-recognition performance is 94 percent or better. If the score is poorer than 94 percent, then a modified psychometric function is generated using the initial presentation level (e.g., 40-dB SL; comfort level) as the starting point. Presentation of 25 words at 6 dB above and below the initial level with less than 6 percent score improvement indicates the initial level yielded maximum word-recognition performance. However, if ≥ 6 percent improvement is found at the first 6-dB increment, then there must be further exploration with another 25 words at an added 6-dB increment. (For example, initial presentation level of 50-dB HL = 80 percent; at 56-dB HL = 88 percent; at 62-dB HL = 84 percent.) The estimate of maximum word-recognition performance then is obtained from a 50-word list presented at the level from the modified psychometric function yielding the highest percent correct.

(c) Contralateral masking must be used whenever there is a ≥ 40 -dB difference between presentation level in the test ear and bone-conduction thresholds at 500, 1000, 2000 Hz in the non-test ear. The masking level required in these instances is presentation level minus 40 dB (average interaural attenuation level) plus the largest air-bone gap at 500, 1000, 2000 Hz in the non-test ear.

(d) "Roll-over" of the psychometric function for word recognition should be derived from 50 words presented at 90-dB HL with appropriate contralateral masking. Roll-over is indicated as WNL or ABN in the upper PI/PB box on VA Form 10-2364. A ≥ 0.25 roll-over ratio (calculated as maximum performance minus minimum performance divided by the maximum performance) is abnormal and should be recorded in the lower PI/PB box on VA Form 10-2364 (Bess, Josey, and Humes, 1979).

(6) Acoustic Immittance Measures.

(a) A 220-Hz probe tone should be used to record a tympanogram from each ear between +200 and -200 daPa or mmH_O. The following three values should be extracted from the tympanograms and recorded on VA Form 10-2364: 1 estimate of ear-canal volume (PVT) (in cm³) at +200 daPa or mmH_O; 2 estimate of the resting middle-ear pressure (in daPa or mmH_O) from tympanometric peak; and 3 a compliance measurement which is calculated by subtracting the volume estimate from the tympanometric peak value.

(b) The acoustic-reflex threshold and adaptation measures should be made with the ear-canal pressure adjusted to the peak of the tympanogram. The maximum level of the reflex-activator signal should not exceed 105-dB HL. Contralateral reflex thresholds should be obtained at 500, 1000, 2000, and 4000 Hz; reflex adaptation should be measured 10 dB above the contralateral reflex thresholds for a 10-s activator signal at 500 and 1000Hz. Reflex adaptation is classified as normal (WNL) if the response magnitude is maintained or as abnormal (ABN) if the response magnitude decreases to one half of maximum within 5 s (Anderson, Barr, & Wedenberg, 1969). Ipsilateral acoustic-reflex thresholds should be obtained at 500, 1000, and 2000 Hz.

(c) Absent acoustic reflexes are indicated with a "+" after the maximum allowable limit (i.e., 105+) or after the maximum output of the measurement device (e.g., 90+).

(7) Non-Organic Testing.

(a) A Stenger or Modified Stenger Test must be administered whenever pure-tone, air-conduction thresholds at 500, 1000, 2000, 3000, and 4000 Hz or the SRTs differ by 20 dB or more between the two ears. If the Stenger is positive, then the Stenger interference levels (SIL) should be indicated on the VA Form 10-2364.

(b) When behavioral thresholds are unreliable or the Stenger Test is inappropriate, auditory evoked potentials may be used to estimate thresholds. These thresholds should be indicated as ABR (auditory brainstem response), MLR or 40 Hz MLR (middle latency response), and LLAEP (long latency auditory evoked potential).

(c) It is not sufficient merely to detect the existence of non-organicity; repeated attempts must be made to determine true organic thresholds. The results of special procedures, unwillingness to respond or cooperate, inter-test inconsistencies, etc., should be documented on the VA Form 10-2364 under "comments".

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5. RESCISSIONS: This VHS&RA Circular will expire September 25, 1990.

6. FOLLOW-UP RESPONSIBILITY: Director, Audiology and Speech Pathology (126).

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HEARING AID DISPENSING PRACTICES: THE ROLE OF AUDIOLOGY

WRITTEN TESTIMONY OF THE AMERICAN ACADEMY OF AUDIOLOGY

INTRODUCTION

The following has been prepared by the American Academy of Audiology to supplement the testimony presented to the Senate Committee on Aging, in an effort to more fully inform the Congress regarding the current system for delivery of hearing aids, including the role of the audiologist, provide further recommendations to improve that system and protect the consumer, and to place basic hearing care and hearing aids in the broader context of health care reform.

The American Academy of Audiology (AAA) represents 5000 audiology practitioners in the United States. Founded in 1988, the AAA is dedicated to the continued improvement of hearing care services and programs offered to the American public. One of the guiding principles of the AAA is "to improve service to the hearing impaired by advancing the highest professional standards for diagnosis, habilitation, rehabilitation, and research in hearing and its disorders." These principles apply specifically, and most importantly, to aged individuals because they compromise more than half of the hearing impaired population in the United States and their numbers are increasing dramatically. The AAA is committed to fostering excellence in hearing care for senior citizens (Appendix A: Task Force on Hearing Impairment in Aged People, American Academy of Audiology)¹. Members of the AAA subscribe to a Code of Ethics which requires honesty, compassion and competence in the delivery of hearing care services (Appendix B: Code of Ethics, American Academy of Audiology)².

AUDIOLOGISTS - PROVIDERS OF HEARING CARE

Currently, there are about 11,000 audiologists in the United States. Audiologic training generally consists of completion of a prescribed program of study, including both didactic coursework and practical experience, culminating in a graduate or professional degree from an accredited University. A sample curriculum, from an accredited training program, can be found in Appendix C (Curriculum leading to a Master's Degree in Audiology, University of Louisville). Coursework includes anatomy, physiology and pathology of the auditory system, differentiation of disease processes of the ear, basic and advanced assessment techniques of hearing evaluation including the electrophysiologic evaluation of the auditory system, techniques in the assessment of the vestibular (balance) system, evaluation and fitting of hearing aids or other assistive listening devices, special techniques to evaluate the pediatric population, methods of hearing conservation including those mandated by the government, acoustics and speech perception, normal and abnormal speech and language development, and intervention and rehabilitation programs for the deaf and hearing impaired. Practical experience with children and adults, in a variety of settings, is required prior to graduation.

Audiology graduate students receive extensive training and coursework in etiology, clinical and audiological manifestations, as well as progression of diseases of the ear, including (but not limited to) presbycusis (age-related hearing loss), ototoxicity, otosclerosis, Paget's disease, vestibular schwannoma, Meniere's Disease, and otologic autoimmune disorders. Audiologists are trained to interpret audiological, electrophysiological and vestibular tests performed in light of differential diagnosis (re: site of lesion) on referral from and to the medical profession. This is routine in the training and practice of audiology today.

Audiologists have course study and clinical instruction in the audiological manifestations of systemic and neurological disorders. Neurologists will agree that audiological and electrophysiological evaluations performed by audiologists are critical to the work-up for patients with neuromuscular disorders, multiple sclerosis and other demyelinating diseases, many of whom do not present with complaints of hearing loss. The utilization of audiological procedures for assessment of non-otologic disorders (e.g. acoustic reflex for facial nerve paralysis) are also included in the coursework and training of an audiologist. Audiologists are trained to perform otoscopic examinations, as part of the comprehensive audiological assessment. All audiologists own or have access to an otoscope. Many audiology clinics have a video-otoscope, a device that allows both documentation and patient education. Graduate training in audiology includes instruction and coursework on the identification of the eardrum, other otologic landmarks, and otoscopic abnormalities.

Otoscopy coupled with the routine use of immittance testing (middle ear function) assures that pathologies of the external or middle ear will not be overlooked by the audiologist. When evidence of middle ear pathology is present, the audiologist is required by professional ethics, as well as by state regulation, to make a medical referral. As evidenced by the dearth of negligence cases associated with audiologists, these conditions are rarely missed.

To become a licensed or certified practitioner generally requires the passing of a national examination and the completion of one year of supervised experience following graduation. Currently, programs of study in Audiology are being revised to reflect a greater commitment to the education and training of audiologists. In the future, the master's degree (2 year post-bachelor's degree) will be eliminated and a doctoral degree (4 year post-bachelor's degree) will be required for entry into audiology practice. (Appendix D: Improving Educational Standards for Audiology)¹⁴.

ROLE AND SCOPE OF AUDIOLOGIC PRACTICE

In addition to the evaluation and dispensing of hearing aids, the services and programs provided by audiologists include the general assessment of hearing, determination of hearing levels in the newborn and infant, screening and hearing assessment in both public and private schools, determination of the cause and location of hearing loss, evaluation and fitting of other assistive listening devices, assessment of balance and vestibular disorders, monitoring of the auditory system during surgical procedures, management of hearing conservation programs in industry and the military, and development and implementation of rehabilitative programs for the deaf and hearing impaired (Appendix E: Scope of Practice, American Academy of Audiology)⁵.

Audiologists provide clinical and academic training to students in audiology. Audiologists teach medical students, residents and physicians about the assessment of hearing and non-medical and non-surgical treatment of hearing loss, including hearing aids. They also provide information and training on all aspects of hearing and vestibular function and communicative disorders and rehabilitation to other professionals including psychology, counseling, rehabilitation and education. Audiologists also provide information and services to business and industry.

Audiologic practice settings include private and government (Veteran's Administration) hospitals, physician practices, the military, public and private schools, and independent private practice. Audiologists are licensed in 43 states (pending in others) as independent providers of hearing care services.

MANDATES FOR AUDIOLOGIC SERVICES

Further evidence for the expertise of audiologists as hearing care providers stems not only from the opinions of the organization and membership of the American Academy of Audiology, but is mandated by programs and laws of the federal government, including the U.S. Public Health Service and the National Institutes of Health, the Department of Labor and the Occupational Safety and Health Administration, and Public Laws 92-142 and 99-457. For example, realistic targets for creating a healthier society have been proposed in the report *Healthy People 2000*, issued by the U.S. Public Health Service⁶. The objectives of this report include reduction of the proportion of workers exposed to excessive daily noise levels (section 10.7), reduction of significant hearing impairment (Section 17.6), an increase in the proportion of primary providers who refer children and older adults for screening and/or assessment of hearing loss (Section 17.15), reduction in the average age of identification of hearing loss to less than 12 months (Section 17.16), and reduction of the number of days of school absenteeism due to middle ear infections (Section 20.9). The audiologist has already assumed the primary responsibility to meet some of these goals, for example the provision of school hearing services. The National Institute on Deafness and Other Communicative Disorders recently proposed that all children born in the United States be screened for hearing loss⁷. Again, the responsibility for the implementation of these programs falls to the Audiology profession. The 1983 Hearing Conservation Amendment to the Noise Control Act (29 CFR 1910.95), mandates hearing conservation programs, under the direction of audiologists or appropriately trained physicians, to persons exposed to excessive levels of noise in the workplace⁸. The U.S. military has adopted the Hearing Conservation Amendment guidelines to protect the hearing of servicemen and women, and are implemented under the direction of military audiologists. Public Laws 99-457 and 94-142 both address the educational needs of the handicapped, including the hearing impaired and deaf, and include provisions for audiological services⁹⁻¹⁰.

The Joint Committee on Infant Hearing, represented by members of the American Academy of Audiology, the American Academy of Pediatrics, the American Academy of Otolaryngology, and the American Speech and Hearing Association, issued a policy statement specifying the need for hearing testing in newborns and infants at risk for hearing loss, and that the screening be conducted under the supervision of an audiologist¹¹. The Academy of Pediatrics recommends referral for audiometry for children with a history of ear infections¹². The American Academy of Audiology recommends an aggressive posture for the identification and remediation of hearing loss in the aged population particularly with the expected significant increase in this population over the next decade¹.

Screening and evaluation of hearing in the newborn, hearing conservation programs in industry and the military, screening children and infants for middle ear disease, or

management of rehabilitation programs for the hearing impaired child or adult have unequivocally been assumed by the audiology profession. Few physicians (primary care or otolaryngologists) are actively involved in these programs. Non-audiologist hearing aid dispensers by definition cannot and do not include these activities as part of their business.

DELIVERY OF HEARING AIDS AND RELATED SERVICES

Among the recommendations presented to the Senate Committee on Aging was the need to develop uniform standards and procedures for the dispensing of hearing aids. The initial step in this process is the hearing evaluation. The evaluation of hearing should be considered as seriously as any other evaluation used to determine physical function and/or status. Although eventually the information from a hearing evaluation may be used to determine the appropriate hearing aid, the initial use is to determine the extent and type of hearing loss, and whether further evaluation, including referral to a physician, is indicated. As such, the hearing evaluation should focus initially, not on the need for amplification, but on the determination of hearing status of the patient.

A hearing examination should include a complete history, visual inspection of the ear canal and ear drum, and tests to identify the amount and type of hearing loss. These tests are part of a comprehensive audiological assessment. More importantly, this evaluation must be conducted by an individual trained to interpret the results, not in the context of the need for a hearing aid, but rather in the context of determination of the status of the ear and hearing of that individual. If the hearing evaluation identifies signs, symptoms or conditions that indicate the need for physician consultation, then the appropriate referral should be made.

Age-related changes in hearing constitute the majority of all hearing losses. Only a small percentage of adult individuals have hearing losses that are amenable to medical or surgical treatment. This is particularly true for the elderly where hearing loss is more a sign of the aging process than a symptom of medical illness. Regardless, hearing loss can be a symptom of a more serious disease process such as AIDS, diabetes or multiple sclerosis. The hearing problems associated with these diseases however, are generally further complications of an already diagnosed condition, and therefore it is extremely unlikely that patients having these diseases would present initially with a symptom of hearing loss in the absence of other symptoms. Nonetheless, the academic and practical training of an audiologist prepares an individual to recognize disease symptoms and determine the need for medical referral. The graduate degree programs include coursework and experience in the identification of the etiology and pathology of hearing loss, the identification of signs and symptoms that signal the need for medical referral, and the decision processes related to the ability to reach these conclusions.

It is important to note that the purpose of medical clearance prior to hearing aid use is

to ensure there is no medical condition which requires treatment. The need for amplification is determined by the comprehensive audiological (hearing) evaluation.

Once the audiological evaluation is complete the evaluation progresses to the need for amplification. In consultation with the patient, the benefit that amplification can provide can be discussed. An important distinction should be made between the benefit provided by amplification and patient satisfaction. Hearing aid benefit refers to the improved utilization of the auditory sense, whether by being able to better understand speech, improved hearing sensitivity or improved social interactions. Satisfaction relates to the consumer perception and judgement regarding that benefit. The consumer considers factors in addition to the benefit when judging satisfaction. These factors include the manner and style of the professional services, the cost/benefit ratio, long term service issues, and personal lifestyle concerns. Ideally, the provision of hearing care should target both benefit and satisfaction as the appropriate outcome of the delivery of hearing aids to a consumer.

HEARING CARE SERVICES AND HEALTH CARE REFORM

Access to hearing care services currently occurs through multiple entry points, including audiologists, primary care physicians (internal medicine and family practice), Otolaryngologists, and hearing aid dispensers. A hearing loss not treatable by medical or surgical means should be referred to the audiologist for management with hearing aids or other assistive devices. A patient with a medically or surgically treatable hearing loss should be referred to an otolaryngologist. However, patients seen by primary care specialists are often referred only to the otolaryngologist for further evaluation, even if the complaint is simply hearing loss. For example, the wife who questions her husband's ability to hear is first referred to the otolaryngologist, then on to the audiologist for a hearing evaluation. Given the relatively low incidence of treatable ear disease in persons complaining of ear or hearing problems¹³, costs could be lowered and patients better be served by direct referral to the audiologist, or by having patients with complaints of hearing problems be initially seen by an audiologist. If the majority of hearing losses are not treatable by medical or surgical means, then significant cost is added to the system by having patients visit physicians prior to determination of the audiologic profile of the patient.

Although systematic studies of the potential cost savings from utilization of the audiologist as entry level providers have not been completed, data from the vision care area shows that the non-physician professional, i.e. the optometrist, provides services at lower costs and with greater access to services. Fees for comparable services were actually lower when provided by optometrists than when provided by ophthalmologists, and patients could be seen sooner by the optometrists¹⁴. While physicians generally object to direct-access to non-physician providers, numerous studies demonstrate firm support and confidence, on the

part of patients, for direct-access to non-physician providers¹⁵⁻¹⁶. The AARP, SHHH, and the Commissioner of the Food and Drug Administration all testified before the Senate Committee on Aging regarding their confidence in Audiologists ability to provide hearing care services.

The optometrist serves an important role in vision care by providing increased accessibility through lower costs but without a sacrifice in quality. Expanding the role of the audiologist in the provision of hearing care should also result in greater accessibility, reduced cost, and with no sacrifice in quality of services provided. The freedom to serve as an entry point into health care, like that provided by the optometrist, expands the choices of the American public, results in competition thus further lowering costs, and increases accessibility through the lowered costs and increased number of providers.

In addition, the recognition of hearing evaluations as part of the basic benefits package of proposed health programs can further serve to lower the direct costs of health care to the American public. Currently, hearing tests and hearing aids are not considered to be services covered by insurance, including Medicare, except in the situation where the tests are necessary for a treatable ear disease. Unfortunately, a hearing test is necessary prior to the determination of whether a specific hearing loss is treatable. Audiologic (hearing) evaluations are designed to assist in this determination. For example, if an elderly patient sees a hearing care provider, regardless if that provider is an audiologist or otolaryngologist, with a primary complaint of hearing loss, a hearing test is required to determine if the loss is treatable. If it turns out that the loss is treatable, then the audiology service is covered by Medicare. If the results of the test show that the loss is not treatable, then the hearing test is not considered a covered service. The determination as to whether this is a covered service is made after the service has been performed. Medicare assumes that the results of a hearing test that reveal non-treatable hearing loss are to be used for acquisition of a hearing aid, a product not covered by this program. For that elderly individual, incorrectly assuming the services are covered by Medicare, the hearing tests become an out-of-pocket expense.

SUMMARY AND RECOMMENDATIONS

Hearing loss can be of serious concern to an aged individual. The hearing care delivery system in the United States, including the provision of hearing aids, can be improved by the implementation of practices which increase consumer satisfaction and ensure the delivery of high quality professional services. The American Academy of Audiology supports efforts made by Congress and the Food and Drug Administration to improve oversight and regulatory activity in this area in an effort to protect the consumer from fraudulent or negligent practices.

The American Academy of Audiology supports the recommendations of consumer organizations, professional groups and the Food and Drug Administration designed to improve the delivery of hearing aids to the American public.

- Audiologists should be recognized as appropriate hearing care providers for the evaluation of hearing, determination of hearing aid candidacy and the fitting of hearing aids. Testimony presented to the Special Committee on Aging shows firm support for the prominent position of the audiologist in the hearing aid delivery area. Issues in health care reform, including cost reduction, quality and access, further argue for the role of the audiologist in the delivery of hearing care services to the elderly.
- Fraudulent practices and representation relating to the use or benefits of hearing aids should be prohibited. Protection of the consumer, particularly in the use of a medical device, must be paramount. Solicitation and door-to-door selling practices should be restricted. Mandates for warranties, right to cancel purchases and specified trial periods should be approved.
- The regulatory boards and agencies responsible for monitoring hearing aid practices at the state level should be strengthened and empowered to police hearing aid practices in their respective states. This will further serve to protect consumers from fraudulent practices and safeguard their health by ensuring appropriate referral for medical evaluation if necessary.
- The consumer must be educated regarding their rights, the potential benefit and satisfaction afforded by hearing aids, strengths and limitations of amplification systems, and the hearing care system. The American Academy of Audiology recognizes and accepts it's responsibility in this area, and will continue to address the need to educate the American public regarding the hearing aid delivery system.
- National standards for both hearing evaluations relative to diagnostic testing and hearing aid fittings, as well as appropriate competencies of the professionals who dispense hearing aids, should be developed. Appropriate licensure requirements should be adopted in every state.

The American Academy of Audiology appreciates the opportunity to supplement the written and oral testimony presented to the U.S. Senate Special Committee on Aging. The American Academy of Audiology stands ready to work with the Congress, the Food and Drug Administration, consumer organizations, professional groups, and state agencies in efforts to improve the delivery of hearing care services to the American consumer.

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APPENDIX A



POSITION STATEMENT

Task Force on Hearing Impairment
in Aged People

Background

One of the demographic imperatives affecting the United States' present and future course is the aging of Americans. The number of persons aged 65 years and older is growing more rapidly than the rest of the U.S. population.²⁰ The expansion of the nation's aged population has considerable implication for health status, health care utilization, and health care delivery.

Hearing impairment is the third most commonly reported chronic problem affecting the aged population.¹⁷ At present, more than 7 million aged persons suffer from some degree of hearing impairment.⁸ Given the rapid growth in the population over 75 years of age, it is projected that more than 11 million members of this age group will have significant hearing impairments by the turn of the century. The aging of the population will be accompanied by an increase in the prevalence and severity of hearing loss, due to the direct correlation between age and hearing loss.

Presbycusis often is defined as hearing loss associated with the aging process. However, the Committee on Hearing, Bioacoustics and Biomechanics³ considers presbycusis to be the sum of hearing losses which result from several varieties of physiological degeneration. These include insults due to noise exposure, ototoxic agents, polypharmacy, and medical disorders as well as the effects of physiological aging.⁹ Irrespective of the etiology, the interference with communication created by sensorineural hearing impairment has a profound negative effect on the lives of aged persons. In addition to its threat to personal safety, hearing impairment has an adverse effect on physical, cognitive, emotional, social, and behavioral function.^{15,1} These manifestations are often viewed by the hearing impaired person as representing a very significant handicap, despite the audiological appearance of a relatively mild hearing loss.¹⁵ Fortunately, the negative influences of hearing impairment are amenable to intervention.¹⁵ Hence, hearing health care professionals must strive to identify individuals with hearing impairments in order to remediate the permanent impact of hearing loss.

Identification of Impairment in the Aged Population

The U.S. Preventive Services Task Force²¹ has recommended that aged persons be screened for hearing impairment. The goal of any screening program is to reach as large a proportion of the eligible target population as possible. To this end, a number of potential settings are available for screening aged individuals for hearing impairments and handicaps. Potential settings for screening include health fairs, community based programs, primary care physician's offices, acute care settings, nursing facilities and possibly the home. Each of these settings has advantages and disadvantages, with the limiting factors in any screening setting being ambient noise level, professional resources available to administer the screen, and money available to purchase the requisite equipment. Nevertheless, a screening program should use tools that are appropriate for the particular setting, and should employ professionals who are well trained to perform the screen. Screening conducted in the offices of primary care physicians is particularly attractive because most persons over 65 years old visit their primary care physician on an annual basis and the office may provide a relatively quiet setting for screening.

A number of screening tools are available to detect clinically important hearing impairments and handicaps in aged people. An impairment is defined as "any loss or abnormality of psychological, physiological or anatomical structure or function," whereas a handicap is "a disadvantage for a given individual resulting from an impairment that limits

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or prevents the fulfillment of a role that is normal for that individual".²⁴ Screening tools designed to detect hearing handicaps and impairments fall into two broad categories: hearing handicap scales and audometric screening.

Hearing handicap scales assess the perceived effects of hearing loss on various aspects of daily function. A screening version of one such scale, the Hearing Handicap Inventory for the Elderly (HHIE-S), is a reliable and valid method for identifying handicapping hearing impairment among aged persons.^{12, 25} The sensitivity and specificity rates of this tool are approximately 70 to 80% for identifying hearing losses of moderate or greater severity.

An audometric screen is a quick and valid method for detecting hearing impairment among aged individuals. Screening for hearing impairment requires the use of one of two methods: 1) a calibrated audiometer in a quiet environment, or 2) an otoscope with a built-in audiometer (e.g., audioscope). The advantage of using a calibrated audiometer is that it is a valid and reliable technique. The requirement of a quiet environment, however, may not be practical in all settings. The audioscope delivers selected frequencies (500, 1000, 2000, and 4000 Hz) at one of three intensities to the entrance of the ear canal. The audioscope has an overall accuracy for hearing screening of 75-80%.^{2, 5, 13} Screening with both a hearing handicap scale and either an audiometer or audioscope is recommended,²² because the correlation between hearing impairment and handicap is imperfect.¹⁸ Thus, combining the two techniques may increase the overall accuracy of the screening program.¹²

Once identified through a screening program as being likely to have a hearing impairment or handicap, an aged person should be referred to an audiologist for thorough audiological evaluation and appropriate recommendations for aural rehabilitation. Medical clearance should also be obtained to rule out pathological conditions that would contraindicate hearing aid use. Unfortunately, the rate of compliance with the recommendation for further audometric evaluation among aged persons can be as low as 50% and ranges between 50 and 90%.^{10, 11, 19} Moreover, in most circumstances, only 10 to 20% of this population subsequently obtains hearing aids. Barriers to compliance include confusion about the hearing aid delivery system, the cost of evaluation and hearing aids, social stigma, unwanted amplification of background noise, and myths about the efficacy of hearing aids.⁴ An integral part of any screening program should be mechanisms to enhance the probability that individuals will comply with referrals for additional evaluation and remediation.

Strategies for Intervention

The audiological evaluation establishes the need for possible aural rehabilitation and medical evaluation. In most cases, the aged person's auditory capabilities can be

assessed with standard audometric techniques. Occasionally, the behavioral assessment must be modified to accommodate physical or cognitive limitations of aged individuals. The typical presbycusis hearing loss is sensorineural, sloping, and ranges in degree from mild to moderately severe.^{7, 14} Moreover, pure tone sensitivity tends to deteriorate with age, and males exhibit poorer thresholds than females of comparable age.^{7, 14} The hearing loss observed in older people often limits their reception of conversational speech, especially in noisy environments.⁴ While the typical presbycusis hearing loss is not amenable to medical intervention, the handicapping effects of the hearing impairment often can be remedied successfully with selected audologic intervention strategies.

Hearing aids are the principal resource for improving communication and reducing handicaps in aged people. Hearing aids amplify speech so that it becomes comfortably audible to the hearing-impaired user but does not exceed the user's tolerance for very loud sounds. Significant improvements in hearing aid design have enabled greater flexibility in selecting hearing aids to fit the typical hearing loss patterns associated with age.⁴ The newest generation of hearing aids includes digitally controlled analog designs. In addition, hearing aids can now be manufactured with manipulation of volume controls, battery compartments, and switches, thereby improving hearing aid use for aged individuals with manual dexterity problems. Recent evidence indicates that hearing aids successfully reduce the social, emotional, and functional handicap often resulting from hearing impairment in aged people.¹³

In addition to hearing aids, assistive living devices can be used effectively by aged people to improve communication in specific situations. Assistive listening devices transmit acoustic signals by wire, magnetic induction, infrared light or radio frequency. They are particularly useful when room acoustics are poor. The use of assistive devices is expanding in theaters, public meeting rooms, and houses of worship. They can be adapted for use in personal living areas and common areas of nursing homes where communication may be difficult.

Alerting devices, which use lights to signal fire alarms or the telephone or doorbell ringing, can reduce the hazards to safety imposed by the hearing loss. Telephone amplifiers with adjustable volume controls are becoming an integral part of many new telephone designs. The television caption decoder can be used by those with reasonable vision, but whose hearing is limited despite rehabilitation. Assistive listening and alerting devices are effective, and their use should be encouraged in hospitals, nursing facilities, and the home.

Hearing aids should be offered within the greater context of aural rehabilitation. Aural rehabilitation includes any non-medical intervention designed to remediate hearing loss and improve communication. It also includes counseling the hearing-impaired person and his or her family about the

implications of hearing impairment, as well as conducting a hearing aid orientation and follow-up to ensure proper hearing aid use. Suggestions for maximizing the use of visual cues and residual hearing are provided. Formal speechreading instruction or auditory training may be recommended to enhance the information received through amplification.

The aural rehabilitation process should include not only the aged hearing-impaired person, but a family member or significant other as well. For the aged individual to achieve maximum benefit, the family and health care staff must appreciate the impact of the hearing impairment, the operation of the amplification device, the benefits and limitations of the procedures being used, and their own role in improving and promoting communication.

Role of the Audiologist

The audiologist is the primary hearing health care provider for aged individuals with hearing impairment. An audiologist is a person who, by virtue of academic and clinical training, and appropriate certification and/or licensure, is uniquely qualified to provide a comprehensive array of professional services relating to the prevention, evaluation, and rehabilitation of auditory impairment and its associated communicative disorders. The audiologist may provide these services independently or as part of an interdisciplinary professional team involved in identification, diagnosis, and treatment of individuals who have disorders related to auditory dysfunction.

The audiologist serves as the primary expert in the assessment and non-medical diagnosis of auditory impairment in aged people. Assessment includes, but is not limited to, the administration and interpretation of behavioral, electroacoustic, and electrophysiologic measures of the status of peripheral and central auditory systems and measures of hearing handicap. Methods of assessment include hearing-handicap scales, pure-tone audiometry, immittance audiometry, speech audiometry, and auditory evoked potential measurement.

Audiologists are uniquely qualified to provide a full range of auditory rehabilitative services to aged individuals. The audiologist is the primary individual responsible for the evaluation and fitting of all types of amplification systems, including hearing aids and assistive listening devices. The audiologist determines whether the aged individual is a suitable candidate for an amplification system, evaluates the benefit that the individual may expect to derive from such systems, and makes an appropriate recommendation. In connection with such recommendations, the audiologist may take ear impressions, fit and dispense the amplification system, and provide counseling regarding its use.

The audiologist also provides rehabilitative services and education to individuals with auditory impairment, to family members, and to the public. The audiologist provides

information concerning hearing and hearing impairment, the use of prosthetic devices, and strategies for improving speech recognition by exploring auditory, visual, and tactile speech information. The audiologist also counsels patients regarding the effects of auditory impairment on communicative and psychosocial status. In addition, the audiologist determines the need for additional aural rehabilitation and, if indicated, the nature of the rehabilitation program. In connection with such determinations, the audiologist may conduct individual and/or group rehabilitation programs.

The audiologist serves as an advocate for aged individuals by encouraging equal access for those with communicative disorders, by prompting "self-help" consumer groups, and by encouraging third-party reimbursement of audiological services. The audiologist should be an integral member of any multidisciplinary team involved in the evaluation of the social, psychological, physical, and mental status of elderly people. The audiologist also serves aged people by promoting awareness of hearing impairment, available audiological services, and available remediation devices and programs to the hearing-impaired individuals, their spouses and children, and to other caretakers who constitute their support system.

Recommendations

The membership of the American Academy of Audiology seeks to maximize communication skills in aged hearing-impaired individuals. A comprehensive approach for providing effective services to aged individuals involves cooperative efforts among a variety of professional organizations and specialists. As a consequence, the Academy membership actively pursues close professional ties with other gerontology specialists toward meeting the hearing health care needs of aged people.

The American Academy of Audiology has developed five recommendations for improving the quality of life for hearing-impaired aged individuals.

1. The Academy advocates the use of screening procedures for identifying persons with hearing impairment or hearing handicap. Screening procedures should be used to identify the greatest number of hearing-impaired aged people. Screening should be coupled with efforts to maximize compliance with referral recommendations for audologic or medical evaluation.
2. The Academy promotes the provision of high quality audiological services for aged people. State-of-the-art knowledge and technology should be applied in the evaluation of hearing impairment in aged individuals as well as in the selection of aural rehabilitative procedures, including hearing aids, for aged individuals.
3. The Academy promotes funding for research on hearing impairment and aging by government agencies and private foundations. Critical issues that need investigation include prevention of age-related hearing loss, understanding the

auditory degenerative processes that account for age-related hearing loss, improving the design of hearing aids to overcome specific speech understanding problems of aged people, and developing valid outcome measures of audiological management strategies.

4 The Academy promotes equitable third-party payment from insurance companies, retirement health plans, state agencies, and federal agencies for hearing-related services and devices for aged people. The limited financial resources of many older people often restrict access to effective audiological services and therefore prevent them from receiving the benefits of a hearing aid.

5 The Academy promotes public education about hearing impairment in aged Americans. Practical information and suggestions should be provided to this group, including warning signs of hearing loss, where to go for help, and the benefits of amplification. Common misconceptions about hearing impairment and hearing aids also need to be dispelled. The Academy was founded in 1988 to "improve service to the hearing impaired by advancing the highest professional standards for diagnosis, habilitation, rehabilitation, and research in hearing and its disorders."⁹ These guiding principles apply specifically, and most importantly, to aged individuals, because they comprise more than half of the hearing-impaired population in the United States and their numbers are increasing dramatically. The American Academy of Audiology is committed to fostering excellence in hearing health care for senior citizens.

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This report was prepared by the following Academy Task Force Members: Sandra Gordon-Salant, (Chair), Frank Balostozky, Michael Lichtenstein, Brad Stach, and Barbara Weinstein. Published in *Audiology Today*, Volume 3, No. 6, November-December, 1991



APPENDIX B

CODE OF ETHICS AMERICAN ACADEMY OF AUDIOLOGY

PREAMBLE

The Code of Ethics of the American Academy of Audiology specifies professional standards that allow for the proper discharge of audiologists' responsibilities to those served and that protect the integrity of the profession. The Code of Ethics consists of two parts. The first part, the Statement of Principles and Rules, presents precepts that members of the Academy agree to uphold. The second part, the Procedures, provides the process which enables enforcement of the Principles and Rules.

PART I STATEMENT OF PRINCIPLES AND RULES

- PRINCIPLE 1: Members shall provide professional services with honesty and compassion and shall respect the dignity, worth, and rights of those served.
 - Rule 1a: Individuals shall not limit the delivery of professional services on any basis that is unjustifiable, or irrelevant to the need for the potential benefit from such services.

- PRINCIPLE 2: Members shall maintain high standards of professional competence in rendering services, providing only those professional services for which they are qualified by education and experience.
 - Rule 2a: Individuals shall use available resources, including referrals to other specialists, and shall not accept benefits or items of personal value for receiving or making referrals.
 - Rule 2b: Individuals shall exercise all reasonable precautions to avoid injury to persons in the delivery of professional services.
 - Rule 2c: Individuals shall not provide services except in a professional relationship, and shall not discriminate in the provision of services to individuals on the basis of sex, race, religion, national origin, sexual orientation, or general health.
 - Rule 2d: Individuals shall provide appropriate supervision and assume full responsibility for services delegated to supportive personnel. Individuals shall not delegate any service requiring professional competence to persons unqualified.
 - Rule 2e: Individuals shall not permit personnel to engage in any practice that is a violation of the Code of Ethics.
 - Rule 2f: Individuals shall maintain professional competence, including participation in continuing education.

- PRINCIPLE 3: Members shall maintain the confidentiality of the information and records of those receiving services.
 - Rule 3a: Individuals shall not reveal to unauthorized persons any professional or personal information obtained from the person served professionally, unless required by law.

- PRINCIPLE 4: Members shall provide only services and products that are in the best interest of those served.
 - Rule 4a: Individuals shall not exploit persons in the delivery of professional services.
 - Rule 4b: Individuals shall not charge for services not rendered.
 - Rule 4c: Individuals shall not participate in activities that constitute a conflict of professional interest.
 - Rule 4d: Individuals shall not accept compensation for supervision or sponsorship beyond reimbursement of expenses.

- PRINCIPLE 5: Members shall provide accurate information about the nature and management of communicative disorders and about the services and products offered.

- Rule 5a:** Individuals shall provide persons served with the information a reasonable person would want to know about the nature and possible effects of services rendered, or products provided.
- Rule 5b:** Individuals may make a statement of prognosis, but shall not guarantee results, mislead, or misinform persons served.
- Rule 5c:** Individuals shall not carry out teaching or research activities in a manner that constitutes an invasion of privacy or that fails to inform persons fully about the nature and possible effects of these activities, affording all persons informed free-choice of participation.
- Rule 5d:** Individuals shall maintain documentation of professional services rendered.
- PRINCIPLE 6:** Members shall comply with the ethical standards of the Academy with regard to public statements.
- Rule 6a:** Individuals shall not misrepresent their educational degrees, training, credentials, or competence. Only degrees earned from regionally accredited institutions in which training was obtained in audiology, or a directly related discipline, may be used in public statements concerning professional services.
- Rule 6b:** Individuals' public statements about professional services and products shall not contain representations or claims that are false, misleading, or deceptive.
- PRINCIPLE 7:** Members shall honor their responsibilities to the public and to professional colleagues.
- Rule 7a:** Individuals shall not use professional or commercial affiliations in any way that would mislead or limit services to persons served professionally.
- Rule 7b:** Individuals shall inform colleagues and the public in a manner consistent with the highest professional standards about products and services they have developed.
- PRINCIPLE 8:** Members shall uphold the dignity of the profession and freely accept the Academy's self-imposed standards.
- Rule 8a:** Individuals shall not violate these Principles and Rules, nor attempt to circumvent them.
- Rule 8b:** Individuals shall not engage in dishonesty or illegal conduct that adversely reflects on the profession.
- Rule 8c:** Individuals shall inform the Ethical Practice Board when there are reasons to believe that a member of the Academy may have violated the Code of Ethics.
- Rule 8d:** Individuals shall cooperate with the Ethical Practice Board in any matter related to the Code of Ethics.

PART II PROCEDURES FOR THE MANAGEMENT OF ALLEGED VIOLATIONS

INTRODUCTION

Members of the American Academy of Audiology are obligated to uphold the Code of Ethics of the Academy in their personal conduct and in the performance of their professional duties. To this end it is the responsibility of each Academy member to inform the Ethical Practice Board of possible Ethics Code violations. The processing of alleged violations of the Code of Ethics will follow the procedures specified below in an expeditious manner to ensure that violations of ethical conduct by members of the Academy are halted in the shortest time possible.

PROCEDURES

1. Suspected violations of the Code of Ethics should be reported in letter format giving documentation sufficient to support the alleged violation. Letters must be signed and addressed to:

Chair, Ethical Practice Board
American Academy of Audiology
6565 Fannin, NA200
Houston, Texas 77030-2707

2. Following receipt of the alleged violation the Board will request from the complainant a signed *Waiver of Confidentiality* indicating that the complainant will allow the Ethical Practice Board to disclose his/her name should this become necessary during investigation of the allegation. The Board may in special circumstances, act in the absence of a signed Waiver of Confidentiality.
3. On receipt of the Waiver of Confidentiality signed by the complainant, or on the decision of the Board to assume the role of active complainant, the member(s) implicated will be notified by the Chair that an alleged violation of the Code of Ethics has been reported. Circumstances of the alleged violation will be described and the member(s) will be asked to respond fully to the allegation.

4. The Chair may communicate with other individuals, agencies, and/or programs, for additional information as may be required for Board review. The accumulation of information will be accomplished as expeditiously as possible to minimize the time between initial notification of possible Code violation and final determination by the Ethical Practice Board.
5. All information pertaining to the allegation will be reviewed by members of the Ethical Practice Board and a finding reached regarding infractions of the Code. In cases of Code violation the section(s) of the Code violated will be cited, and a sanction specified when the Ethical Practice Board decision is disseminated.
6. Members found to be in violation of the Code may appeal the decision of the Ethical Practice Board. The route of Appeal is by letter format through the Ethical Practice Board to the Executive Committee of the Academy. Requests for Appeal must:
 - a. be received by the Chair, Ethical Practice Board, within 30 days of the Ethical Practice Board notification of violation.
 - b. state the basis for the appeal, and the reason(s) that the Ethical Practice Board decision should be changed.
 - c. not offer new documentation.

The decision of the Executive Committee regarding Appeals will be considered final.

SANCTIONS

1. *Reprimand.* The minimum level of punishment for a violation consists of a reprimand. Notification of the violation and the sanction is restricted to the member and the complainant.
2. *Cease and Desist Order.* Violator(s) may be required to sign a Cease and Desist Order which specifies the non-compliant behavior and the terms of the Order. Notification of the violation and the sanction is made to the member and the complainant, and may on two-thirds vote of the Ethical Practice Board be reported in an official publication.
3. *Suspension of Membership.* Suspension of membership may range from a minimum of six (6) months to a maximum of twelve (12) months. During the period of suspension the violator may not participate in official Academy functions. Notification of the violation and the sanction is made to the member and the complainant and is reported in official publications of the Academy. Notification of the violation and the sanction may be extended to others as determined by the Ethical Practice Board. No refund of dues or assessments shall accrue to the member.
4. *Revocation of Membership.* Revocation of membership will be considered as the maximum punishment for a violation of the Code. Individuals whose membership is revoked are not entitled to a refund of dues or fees. One year following the date of membership revocation the individual may reapply for, but is not guaranteed, membership through normal channels and must meet the membership qualifications in effect at the time of application. Notification of the violation and the sanction is made to the member and the complainant and is reported in official publications of the Academy for at least three (3) separate issues during the period of revocation. Special notification, as determined by the Ethical Practice Board, may be required in certain situations.

RECORDS

1. A Central Record Depository shall be maintained by the Ethical Practice Board which will be kept confidential and maintained with restricted access.
2. Complete records shall be maintained for a period of five years and then destroyed.
3. Confidentiality shall be maintained in all Ethical Practice Board discussion, correspondence, communication, deliberation, and records pertaining to members reviewed by the Ethical Practice Board.
4. No Ethical Practice Board member shall give access to records, act or speak independently, or on behalf of the Board, without the expressed permission of the Board members then active, to impose the sanction of the Board, or to interpret the findings of the Board in any manner which may place members of the Board, collectively or singly, at financial, professional, or personal risk.
5. A Book of Precedents shall be maintained by the Ethical Practice Board which shall form the basis for future findings of the Board.

APPENDIX C

SAMPLE CURRICULUM LEADING TO MASTER'S DEGREE IN AUDIOLOGY

**GRADUATE PROGRAM
IN COMMUNICATIVE DISORDERS
DIVISION OF COMMUNICATIVE DISORDERS
DEPARTMENT OF SURGERY
UNIVERSITY OF LOUISVILLE
SCHOOL OF MEDICINE**

Introduction

The School of Medicine's Graduate Program in Communicative Disorders has teaching affiliations with several agencies, hospitals, schools and clinics in the "Kentuckiana" area. All of these practicum sites are within a short automobile ride of the Medical Center, and several sites are located within walking distance. These affiliates provide access to a wide variety of patient populations and stimulating opportunities for research. These sites include, among others, the Veterans Administration Medical Center's Audiology and Speech Pathology Service, the Jefferson County School System, Hazelwood Hospital and Intermediate Care Facility, Humana Hospital-Louisville of Louisville, Norton Hospital, Kosair Children's Hospital, the Department of Pediatrics' Child Evaluation Center, Frazier Rehabilitation Center, University Speech Pathology Associates, University Audiology Associates, the Louisville Deaf-Oral School, the Kentucky Easter Seal Society Hearing and Speech Center, the Children and Youth Treatment Center, Ireland Army Hospital, Fort Knox, and a variety of private practice settings.

The Primary teaching and service clinic of the Graduate Program in Communicative Disorders is the WHAS Crusade for Children Audiology and Speech Pathology Center located in Myers Hall in the Health Sciences Center in downtown Louisville. All graduate students begin their practicum experience in this facility. The Center's faculty, professional staff and students provide approximately 8,000 units of service to patients with speech, language and hearing handicaps each year. The program also operates an active satellite clinic in the Founder's Union Building on the Isaac Shelby Campus of the University of Louisville in Eastern Jefferson County. The WHAS Crusade for Children Audiology and Speech Pathology Center houses three sound-treated audiological test suites and eight speech-language therapy rooms, each of which is equipped with video cameras for use by our supervisory staff. This center also houses special facilities and equipment for advanced clinical applications and research. These include a new laboratory with seven Apple computers for student use, a complete Augmentative (non-vocal) Communication Center which features sophisticated electronic

aids for our speechless patients, a fiber-optic nasopharyngoscope with video stroboscopic capabilities, a computer based evaluation and treatment laboratory for our major cochlear implant program, a speech and hearing science laboratory, an electromyography and brainstem evoked audiometry clinic, a computer assisted probe microphone unit for hearing aid evaluation and fitting, electroacoustic hearing aid analysis equipment, a novel computer-based stuttering rehabilitation clinic, and an active child language disorders program.

The Graduate Program in Communicative Disorders is fully accredited by the Educational Standards Board of the American Speech-Language Hearing Association (ASHA). The program carefully abides by the rigorous ASHA regulations concerning all aspects of curriculum content, practicum supervision, and patient care. The University of Louisville's Graduate Program in Communicative Disorders was the first in the State of Kentucky to receive this honor, and it remains the only ASHA accredited program in audiology in Kentucky. All research conducted by the program's faculty and students is approved by the University's Human Studies Committee and performed in accordance with guidelines laid down by the federal government.

The University of Louisville formally dedicated its \$26,000,000 regional Health Sciences Center on April 4, 1971. This facility, located in downtown Louisville, serves a metropolitan area of approximately one million people. The Health Sciences Center houses the Schools of Medicine, Dentistry, Nursing, Allied Health Professions, and Graduate Programs in several basic and applied health-related disciplines. These facilities accommodate over 1200 students from the Schools of Medicine, Dentistry and other Graduate Programs and more than 500 faculty, staff and research personnel. The Graduate Program in Communicative Disorders is located in this complex in a building which it shares with the Division of Otolaryngology. The Health Sciences Center is a bright new page in the history of the oldest medical school west of the Alleghenies.

Over

Total University of Louisville Library holdings printed in microtext form number approximately 1,100,000 volumes. The University offers an extensive library system designed to support graduate research in a variety of fields. The Main Library houses over 500,000 catalogued volumes. The Kornhauser Health Sciences Library, with acquisitions dating back to the founding of the Medical School in 1837 contains approximately 40,000 monographs and 75,000 volumes of bound journals. Over 1500 journals are received regularly, with complete reference facilities for Audiology and Speech-Language Pathology. This facility is a resource library in the Kentucky-Ohio-Michigan Regional Medical School Library Program which offers an inter-library loan system through which virtually any book, journal or article not available locally can be obtained. MEDLAR searches are provided and MEDLINE, the direct access referral service connected to the National Library of Medicine and Biomedical Data Base, is available. A large variety of audiovisual self-study material is

provided, including audio and video tapes, tape slide units, and eight millimeter cassette films.

Faculty research in the division of Communicative Disorders reflects the diversified clinical populations available in the metropolitan Louisville area. Past and current research in the area of Audiology includes such topics as amplification for the hearing impaired, cochlear implantation, vestibular disease, middle ear reflex phenomenon, electromyostimulation, and noise. In Speech Pathology, areas of research interests include voice disorders, augmentative (non-vocal) communication, closed head injury, head and neck cancer rehabilitation, normal language development and language impaired children. Students are encouraged to participate in faculty research. This provides the student with the opportunity to understand the research process and prepare for initiating their own research if they so desire.

Admission and Requirements



Graduate Program in Communicative Disorders
University of Louisville School of Medicine
Myers Hall
Louisville, Kentucky 40292

Phone (502) 588-5274
Fax (502) 588-0865

Program Descriptions

The Graduate Program in Communicative Disorders at the University of Louisville School of Medicine offers graduate programs leading to the Master of Science degree in Audiology or Speech-Language Pathology. The programs are accredited by the Educational Standards Board of the American Speech-Language-Hearing Association.

Admissions Policy

Applicants must have an undergraduate cumulative GPA of at least 3.0 (on a 4 point system). They must have at least 500 on the Verbal and Quantitative sections (combined) of the GRE, and provide three supportive letters of recommendation from academic sources. Applicants with grades or scores below these minimums will be reviewed by the Program's Admissions Committee for possible probationary admission with conditions. A formal admissions interview may be required of some applicants. The applicant should also read the General Admissions Requirements in the Graduate School Catalogue.

The Preparatory Program

Applicants who do not have an undergraduate degree in speech and hearing will be required to complete the Preparatory Program before being fully matriculated into the M.S. degree program. The Preparatory Program is designed to permit students with non-traditional educational backgrounds to learn more about the fields of Audiology and Speech-Language Pathology, and to provide students with essential background information. The Preparatory Program includes

- CMDS 545 Survey of Communication Disorders & Processes (3)
- CMDS 567 Fundamentals of Speech & Hearing Science (3)
- CMDS 563 Clinical Phonetics (3)
- CMDS 564 Normal Speech & Language Development (3)
- CMDS 557 Aural Rehabilitation (4)
- CMDS 551 Clinical Observations (1)
- Electives: As required for ASHA certification

All coursework in the Preparatory Program will apply to the M.S. degree and ASHA certification.

General Program Requirements

Students must complete a minimum of 41 (Audiology) or 51 (Speech-Language Pathology) credit hours in the Graduate Program and meet the academic and practicum requirements for the Certificate of Clinical Competence (CCC) awarded by the American Speech-Language-Hearing Association. Requirements for the CCC are listed below. They include:

1. **Degree** - Applicants for either certificate must hold a Master's or Doctoral degree. Effective 1/1/94 - All graduate coursework and clinical practicum required in the professional area for which the Certificate is sought must have been initiated and completed at an institution whose program was accredited by the ESB in the area for which the Certificate is sought.

II Academic Coursework - 75 semester credit hours (s.c.h.)

- A Basic Science Coursework (27 s.c.h.)
 - 6 s.c.h. in biological/physical sciences and mathematics
 - 6 s.c.h. in behavioral and/or social sciences
 - 15 s.c.h. in basic human communication processes to include the anatomic and physiologic bases, the physical and psychophysical bases, and the linguistic and psycholinguistic aspects

- B Professional Coursework (36 s.c.h.) - 30 of the 36 s.c.h. in courses for which graduate credit was received, 21 of the 30 s.c.h. must be in the professional area for which the Certificate is sought

CCC-Speech-Language Pathology

- * 30 s.c.h. in speech-language pathology
 - 6 in speech disorders
 - 6 in language disorders
 - 6 s.c.h. in audiology
 - 3 in hearing disorders and hearing evaluation
 - 3 in rehabilitative/procedures

CCC-Audiology

- * 30 s.c.h. in audiology
 - 6 in hearing disorders and hearing evaluation
 - 6 in rehabilitative/procedures
 - 6 s.c.h. in speech-language pathology, not associated with hearing impairment
 - 3 in speech disorders
 - 3 in language disorders

III Supervised Clinical Observation and Clinical Practicum 375 close hours (c.h.)

- A Clinical Observation (25 c.h.)
 - Prior to beginning initial clinical practicum
- B Clinical Practicum (350 c.h. total)
 - 250 c.h. at graduate level in the area in which the Certificate is sought
 - 50 c.h. in each of three types of clinical settings.
- C CCC-Speech-Language Pathology
 - * 20 c.h. in each of the following 8 categories:
 - Evaluation: Speech disorders in children
 - Evaluation: Speech disorders in adults
 - Evaluation: Language disorders in children
 - Evaluation: Language disorders in adults
 - Treatment: Speech disorders in children
 - Treatment: Speech disorders in adults
 - Treatment: Language disorders in children
 - Treatment: Language disorders in adults
 - Up to 20 c.h. in the major professional area may be in related disorders
 - * 35 c.h. in audiology
 - 15 in evaluation/screening
 - 15 in habilitation/rehabilitation

Over

CCC-Audiology

- 40 c.h. in the first 4 categories listed below, 20 c.h. in the fifth category
 - Evaluation: Hearing in children
 - Evaluation: Hearing in adults
 - Selection and Use: Amplification and assistive devices for children
 - Selection and Use: Amplification and assistive devices for adults
 - Treatment: Hearing disorders in children and adults
- Up to 20 c.h. in the major professional area may be in related disorders
- 35 c.h. in speech-language pathology unrelated to hearing impairment
- 15 in evaluation/screening
- 15 in treatment

IV National Examinations in Speech-Language Pathology and Audiology**V The Clinical Fellowship****Thesis Option**

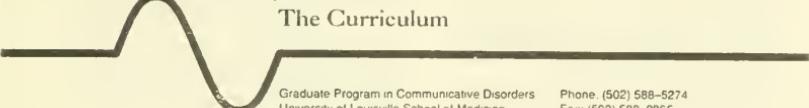
Students may choose either the thesis or non-thesis option. Those choosing to complete a Master's Thesis will take a statistics course above the introductory level and take a comprehensive oral examination over their thesis material only. Non-thesis students will take comprehensive written and oral examinations covering all of their coursework prior to graduation.

Clinical Practicum

ASHA requires a minimum of 375 clock hours of clinical practicum for certification. Thirty-five (35) clock hours must be in the minor area. Two hundred and fifty (250) clock hours must be completed at the graduate level. Students will be required to obtain professional liability (malpractice) insurance prior to engaging in clinical practicum. Insurance applications are available in the Program office.

Teacher Certification

Students who wish to become certified to work in the public schools may need to complete additional general education requirements and student teaching. Details are available in the Program office.



The Curriculum

Graduate Program in Communicative Disorders
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Fax: (502) 588-0865

Audiology Majors

(Example Sequence)

Year 1

Fall	CMDS 572	Anatomy & Physiology (4)
	CMDS 601	Audiology I (4)
	CMDS 605	Hearing Science Laboratory (1)
	CMDS 610	Practicum: Audiology (1)
	CMDS 602	Articulation/Phonology (3)*
Spring	CMDS 651	Audiology II (4)
	CMDS 557	Aural Rehabilitation (4)
	CMDS 652	Childhood Language Disorders (3)*
	CMDS 630	Amplification Systems (3)
	CMDS 610	Practicum: Audiology (1)
Summer	CMDS 654	Evoked Potentials(2)
	CMDS 672	Vestibular Assessment (2)
	CMDS 610	Practicum: Audiology (2)
	PSYC 312	Intro to Grad. Studies (3)*

Year 2

Fall	CMDS 653	Hearing Conservation (2)
	CMDS 670	Advanced Amplification Concepts (3)
	CMDS 610	Practicum: Audiology (4)
	CMDS 699	Thesis (1-3)**
	CMDS 611	Practicum: Speech Pathology (1) *
	OBIO 501	Biostatistics (3)***
Spring	CMDS 697	Special Topics: Audiology (2)
	CMDS 668	Professional Issues (1)
	CMDS 610	Practicum: Audiology (4)
	CMDS 699	Thesis (1-3)**
		Electives*

* If necessary

** Optional

*** Required for thesis

Speech-Language Pathology Majors

(Example Sequence)

Year 1

Fall	CMDS 572	Anatomy & Physiology (4)
	CMDS 602	Articulation/Phonology (3)
	CMDS 663	Voice Disorders (4)
	CMDS 661	Diagnostics/Clinical Methods I (3)
	CMDS 611	Practicum: Speech Pathology (1)
Spring	CMDS 667	Adult Language Disorders (4)
	CMDS 620	Neurological Disorders (3)
	CMDS 652	Childhood Language Disorders (3)
	CMDS 611	Practicum: Speech Pathology (1)
	CMDS 557	Aural Rehabilitation (4)*
Summer	CMDS 665	Fluency Disorders (3)
	CMDS 690	Head & Neck Disorders (3)
	CMDS 611	Practicum: Speech Pathology (2)
	PSYC 312	Intro to Grad. Studies (3)*

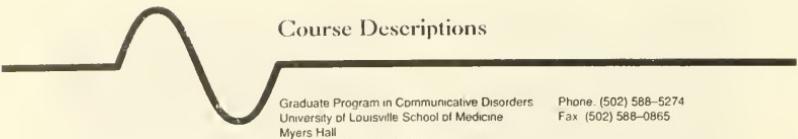
Year 2

Fall	CMDS 671	Diagnostics/Clinical Methods II (2)
	CMDS 696	Augmentative Communication (3)
	CMDS 611	Practicum: Speech Pathology (2)
	CMDS 604	Audiology (4)*
	CMDS 699	Thesis (1-3)**
	OBIO 501	Biostatistics (3)***
Spring	CMDS 695	Special Topics (2)
	CMDS 668	Professional Issues (1)
	CMDS 663	Gerontologic Disorders (2)
	CMDS 664	Management of Public School Caseload (3)**
	CMDS 611	Practicum: Speech Pathology (4)
	CMDS 699	Thesis (1-3)**
		Electives*
	CMDS 610	Practicum: Audiology (1)*

* If necessary

** Optional

*** Required for thesis



Course Descriptions

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Course Descriptions

CMDS 545 Survey of Communication Processes and Disorders (3)

Prerequisites: None

This course provides a general overview and introduction to the scope of practice in Audiology and Speech-Language Pathology, the mechanics of communicative disorders, anatomy and physiology of the speech and hearing mechanism, diagnostic audiology and hearing impairment rehabilitation, normal speech and language development and disorders, and a description of neurogenic disorders.

CMDS 557 Aural Rehabilitation (4)

Prerequisites: None

Overview of historical and current philosophies in the rehabilitation of hearing impaired persons including psychological, sociological, educational and vocational aspects

CMDS 563 Clinical Phonetics (3)

Prerequisites: None

The International Phonetic Alphabet and other symbol systems are utilized in transcription of speech sounds. A description of speech sounds in terms of acoustic and physiologic dimensions. Special Emphasis on speech disorders and dialects

CMDS 564 Normal Language & Speech Development (3)

Prerequisites: None

Study of normal development of language and speech from infancy onward. Includes pragmatics, semantics, syntax, morphology, phonology, and psycholinguistic aspects. Also includes relationships among communication, socialization, cognition, play, and maturation, an overview of dialectical, cultural, and bilingual aspects, and basic language sampling and analysis procedures

CMDS 567 Fundamentals of Speech & Hearing Science (3)

Prerequisites: None

Topics include acoustics, speech sound acoustics and speech production characteristics, co-articulation, biophysics and psychoacoustics of hearing, and instrumentation in the speech and hearing sciences

CMDS 570 Clinical Observation in Speech Pathology & Audiology (1)

Prerequisites: None

Students will complete observations in speech pathology and audiology so that minimum ASHA guidelines will be met. Additional observations may be assigned to introduce students to the variety of practicum opportunities available in the program (Pass/Fail only)

CMDS 572 Anatomy & Physiology for Speech and Hearing (4)

Prerequisites: Undergraduate degree in communicative disorders or CMDS 545 and elective in human biology or equivalent

Structure and function of speech and auditory/vestibular mechanisms. Includes Neuroanatomy/neurophysiology of communication. Emphasis on clinical applications. Dissection of human cadaver material

CMDS 574 Introduction to Research in Speech and Hearing (1-3)

Prerequisites: None

Basic instruction in research techniques in the speech and hearing disciplines including library usage, literature review and statistics. This course does not satisfy the statistics requirements

CMDS 602 Articulation-Phonology (3)

Prerequisites: CMDS 563 and 567 or their equivalents

Includes study of vowel and consonant characteristics, distinctive features, co-articulation, and phonological processes. Addresses the sequence of development of phonology/ articulation from infancy onward, including norms, individual differences, and theories. Procedures for diagnosing disorders in phonology/ articulation. Special emphasis on approaches to therapeutic management

CMDS 604 Audiology I (4)

Prerequisites: CMDS 545 or undergraduate audiology class

Overview of hearing and hearing loss, including introduction to methods of assessment, principles of masking, case history, impedance measurement and screening

CMDS 605 Hearing Science Laboratory (1)

Prerequisites: CMDS 567 or equivalent

Exercises demonstrating basic principles of hearing science as they apply to audiological methods, including perception of tones vs. speech, binaural hearing, masking, difference limen, and neural tuning curves

CMDS 610 Practicum in Audiology (1-4)

Prerequisites: CMDS 604, 567 or equivalent

Clinical training in conventional audiology, advanced diagnostics, patient management, hearing aid evaluation and aural rehabilitation therapy. Advanced students will be assigned to a variety of clinical settings with the consent of the instructor. (Refer to the "Manual for Audiology and Speech Pathology Practicum" for details)

CMDS 611 Practicum in Speech Pathology (1-4)

Prerequisites: CMDS 564, 602

Diagnostic and therapeutic contact with individuals who exhibit communication disorders. Practicum assignments include treatment planning, report writing and patient/parent counseling. Advanced students will be assigned to outside practicum sites with the consent of the instructor. (Refer to the "Manual for Audiology and Speech Pathology Practicum" for details)

CMDS 620 Neurological Disorders of Speech Production (3)

Prerequisites: CMDS 572

Study of disorders resulting in flaccid, spastic, mixed, ataxic, hypokinetic or hyperkinetic dysarthria. Diagnostic and treatment strategies will be covered

CMDS 630 Amplification Systems in Aural Rehabilitation (3)

Prerequisites: CMDS 572, 567 or equivalent, 604

Principles of amplification for the hearing impaired. Psycho-acoustics and electroacoustics pertaining to hearing aid candidacy, evaluation and rehabilitation. Hearing aid selection and fitting strategies. Special applications including assistive listening devices and systems.

CMDS 651 Audiology II (4)

Prerequisites: CMDS 572, 604

Study of diagnostic techniques, including the theory and application of the impedance test battery and site of lesion tests, in the differential diagnosis of otolaryngopathies related to hearing loss in both children and adults

CMDS 652 Childhood Language Disorders (3)

Prerequisites: CMDS 564 or equivalent

Language characteristics of children with specific language disability, acquired aphasia, autism, mental retardation, visual impairment, hearing impairment, learning disabilities, and other handicapping conditions. Assessment procedures and intervention strategies are addressed

Over

CMD5 653 Hearing Conservation (2)**Prerequisites:** CMDS 604

Methods of detection, prevention and monitoring of hearing in special populations, particularly those exposed in the industrial work place. Topics include federal regulations and the effect of noise on humans.

CMD5 654 Evoked Potentials in Audiology (2)**Prerequisites:** CMDS 651

Principles of electrophysiology as applied to assessment of the auditory system includes brainstem auditory evoked potentials; electromyography, middle latency potentials, long latency potentials; hearing assessment, retro-cochlear evaluation and intra-operative monitoring.

CMD5 658 Advanced Concepts in Audiology (1-3)**Prerequisites:** CMDS 651

Study of special areas or new topics in audiology. Previous topical areas include assistive listening devices, central auditory assessment in adults, educational audiology, high frequency audiology, and advanced concepts in impedance.

CMD5 661 Diagnostic/Clinical Methods in Speech Language Pathology I (3)**Prerequisites:** CMDS 545, 563, and 564 or equivalent

Introduction to diagnostic procedures, including interviewing techniques, formal and informal assessment and report writing. Emphasis placed on birth to five population and federal guidelines/implications of PL 94-142 and PL 99-457.

CMD5 663 Voice Disorders (4)**Prerequisites:** CMDS 572 (may be taken concurrently), 567

Analytic studies of voice production including dysphonia, psychogenic disturbance, and resonance disorders. Incorporates laboratory demonstrations and exercises to develop skills in video stroboscopy, videolaryngoscopy, manometry, the VNL-probe, and the Kay Sonograph, Laryngograph, and Nasometer.

CMD5 664 Management of the Public School Caseload (3)**Prerequisites:** CMDS 602 and 652

Course covers information unique to working in a school setting. Topics such as developing and writing Individual Educational Plans, scheduling, identification, establishing a caseload, and other school issues will be discussed.

CMD5 665 Fluency Disorders (3)**Prerequisites:** CMDS 567 or equivalent

Fluency disorders of children and adults. Etiology and theories of dysfluency. Assessment procedures and therapeutic management. Includes a review of current technological applications.

CMD5 667 Adult Language Disorders (4)**Prerequisites:** CMDS 572

Review of the neurological basis of language processing. Special emphasis on the speech and language disorders, diagnosis and remediation of patients experiencing left and right cerebral vascular accidents, and traumatic brain injury.

CMD5 668 Professional Issues in Audiology & Speech Pathology (1)**Prerequisites:** None

Surveys social, political, business and professional issues in health care delivery related to communicative disorders. Topics include: curriculum vitae preparation, professional interviews, professional liaison, contracts and funding sources, quality assurance mechanisms, Medicare/Medicaid guidelines and reimbursement issues, and ASHA Code of Ethics. (Pass/Fail only)

CMD5 669 Assessment and Treatment of Gerontological Communicative Disorders (2)**Prerequisites:** CMDS 620, 667

The normal aging process. Communicative disorders of the aged: especially dementia, multi-infarct lesions, Alzheimer's disease, Parkinson's disease, chorus, metabolic and drug induced delirium.

CMD5 670 Advanced Concepts in Amplification (3)**Prerequisites:** CMDS 630

New trends and developments in amplification technology and applications. Implantable devices, automatic signal processing, digital amplification, programmable instruments, vibro-tactile aids, etc. Developing a dispensing practice: demographics, projections, capitalization, marketing and organization. Ear mold and hearing aid repair, modification and fabrication.

CMD5 671 Diagnostic/Clinical Methods in Speech Language Pathology II (2)**Prerequisites:** CMDS 652 and 661

Advanced study of diagnostic procedures and interpretation with emphasis on school age and adolescent assessment. Specific emphasis on adolescent language/learning disabilities and central auditory processing disorders.

CMD5 672 Assessment of Vestibular System and its Disorders (2)**Prerequisites:** CMDS 651

Review of the interactive balance mechanisms: vestibular, oculomotor and proprioceptive systems. Technologies and procedures for assessing and quantifying disorders of equilibrium, including electromyography, posturography and rotary chair.

CMD5 690 Assessment and Treatment of Head and Neck Disorders (4)**Prerequisites:** CMDS 572

Speech and voice characteristics of oral cancer and laryngectomy patients, dysphagia evaluation and treatment, communication systems for ventilator dependent patients, and an overview of tracheostomy tubes and their functions. Modified barium swallow procedures and the bedside dysphagia examinations.

CMD5 695 Special Topics In Speech and Language Disorders (1-3)**Prerequisites:** permission of instructor

Special areas or new topics in speech language pathology. Topics may include counseling, genetic syndromes, multicultural issues, cerebral palsy, management of the burn patient, new instrumentation, etc.

CMD5 696 Augmentative/Alternative Communication (3)**Prerequisites:** CMDS 652, 690, 696

Augmentative alternative communication (AAC). Topics include identification and assessment of patients needing AAC, requirements and functional dimensions of AAC systems, symbol systems, transmission techniques, and intervention strategies.

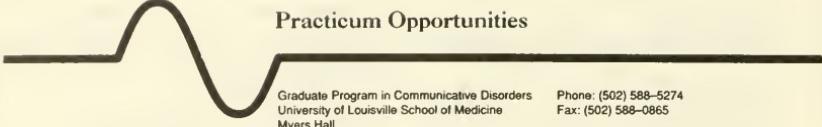
CMD5 697 Special Topics In Audiology (1-3)**Prerequisites:** Consent of instructor

Study of special areas or new topics in audiology not included in other courses, such as current technological, political or economic trends in Audiology.

CMD5 699 Thesis (1-3), Repeatable to a maximum of 6 credit hours**Prerequisites:** By arrangement with instructor. OBO 501 (Biostatistics)

(may be taken concurrently)

Introduction to the scientific research process. Relating research design and data analysis to the research question(s). Manuscript preparation.



Practicum Opportunities

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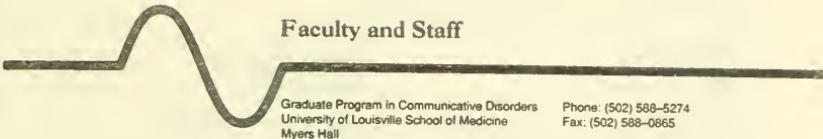
Practicum Sites

University Clinics

- WHAS Crusade for Children Audiology & Speech Pathology Center
 Full range of audiology and speech pathology services for both adults and children
- University of Louisville Shelby Campus Speech Clinic
 Satellite clinic for the WHAS Crusade Audiology & Speech Pathology Center providing speech and language services for the pediatric population in Eastern Jefferson County
- Rauch Rehabilitation Center
 A satellite clinic providing speech and language services for the pediatric population in Southern Indiana
- Ambulatory Care Clinic
 Provides speech pathology and audiology services in conjunction with the ENT Clinic; serves both children and adults
- Humana Hospital-University of Louisville
 Provide speech pathology and audiology services for both inpatients and outpatients

Affiliated Practicum Sites

- University Audiology Associates
 University-sanctioned private practice offices providing a full range of audiological services
- University Speech Pathology Associates
 University-sanctioned private practice offices providing a full range of speech-language services
- Veterans Administration Medical Center
 Provides speech-language pathology and audiology services for adult military veterans
- Frazier Rehabilitation Center
 Provides speech-language pathology services for stroke, head trauma, and degenerative neuro-muscular populations
- Norton-Kosair Children's Hospitals
 Provide audiological services for neonates, children and adults
- Child & Youth Project Department of Pediatrics
 Provides speech-language pathology services for disadvantaged pediatric populations
- Easter Seal Speech and Hearing Center
 Provides a full range of audiological and speech-language pathology services for both adults and children
- Hazelwood ICF/MR
 Provides speech-language pathology and audiological services for mentally handicapped populations of all ages
- Baptist East Hospital: Cynthia Smith & Associates
 Comprehensive inpatient/outpatient facility serving both the pediatric and adult population
- Humana Hospital-Audubon Hospital: JoLynn B. Drury & Associates
 Provides comprehensive audiological and speech-language pathology services for inpatients/outpatients, serving both the pediatric and adult population
- Oldham County School System
 Provides speech-language pathology services for school-aged children and youths ages 0-21 years
- Jefferson County Public School System
 Provide audiological and speech-language pathology services for school-aged children and youths ages 0-21 years
- United Cerebral Palsy KIDS Center
 Provides speech-language pathology services in association with a multi-disciplinary team serving neurological impaired children
- Child Evaluation Center: Department of Pediatrics
 Provides speech-language pathology services in a multi-disciplinary Pediatric Diagnostic Center
- Kentucky Commission for Handicapped Children
 Provides audiological and speech-language pathology services for pediatric populations; specific services for cleft lip/palate, cranio-facial anomalies, and hearing impaired children
- Southeast Rehabilitation Center
 Provides a full range of audiological and speech-language pathology services for both adults and children in a total rehabilitation context
- Louisville Hearing Aid Centers, Inc.
 Provides full range of audiological diagnostic and rehabilitative services for the hearing-impaired, retail hearing aid dispensary
- Kentuckiana Ear, Nose & Throat, P.S.C.
 Private practice facility that provides full range of otologic and audiology services
- Richmond, Peisel and Richmond, P.S.C.
 Private practice facility that provides full range of otologic and audiology services
- Louisville Deaf Oral School
 School setting which provides diagnostic and rehabilitative services for hearing impaired infants through kindergarten age; unique Parent-Infant program
- Louisville Audiology Society Metropolitan Hearing Aid Bank
 Hearing aid services provided to the indigent adult population in the Louisville Metropolitan area



Faculty and Staff

Graduate Program in Communicative Disorders
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Faculty and Staff

Barbara M. Baker, Associate Professor
 Ph.D. (1976); CCC-SLP
 Wayne State University
 Voice; Adult Neuropathology
 Head & Neck Cancer

Nancy P. Browne, Clinical Supervisor
 M.S. (1984); CCC-A
 University of Southern Mississippi
 Adult and Pediatric Audiology

David R. Cunningham, Professor & Chair
 Ph.D. (1972); CCC-A
 University of Kansas
 Amplification Systems; Professional Issues

Karen L. Davids, Clinical Supervisor
 M.S. (1989); CCC-SLP
 University of Louisville
 Pediatric Speech & Language Disorders

Barbara A. Eisenmenger, Clinical Coordinator
 M.S. (1977); CCC-A
 Purdue University
 Aural Rehabilitation; Cochlear Implants

Mary A. Elder, Clinical Coordinator
 M.S. (1988); CCC-SLP
 University of Louisville
 Pediatric Speech-Language Disorders;
 Public School Issues

Lee Ann Golper, Clinical Assistant Prof.
 Ph.D. (1982); CCC-SLP
 University of Oregon
 Voice; Neuropathology

Sherry T. Hoza
 M.A. (1977); CCC-SLP
 George Washington University
 Pediatric Speech-Language Disorders

Andrea L. Jaha, Clinical Supervisor
 M.S. (1980); CCC-SLP
 University of Louisville
 Infant Sensorimotor-Oral Stimulation;
 Pediatric Speech-Language Disorders

Jill H. Newman
 M.S. (1984); CCC-SLP
 University of Louisville
 Pediatric Speech-Language Disorders

George O. Purvis, Clinical Assistant Prof.
 Ph.D. (1973); CCC-A
 University of Kansas
 Electrophysiologic techniques; vestibular
 Disorders

Nancy L. Shaw, Assistant Professor
 Ph.D. (1989); CCC-SLP
 Penn State University
 Child Language Development & Disorders

Sharon L. Vernon, Clinical Supervisor
 M.S. (1975); CCC-SLP
 University of South Carolina
 Adult Speech-Language Disorders

Ian M. Windmill, Associate Professor
 Ph.D. (1983); CCC-A
 Florida State University
 Diagnostic and electrophysiologic
 Techniques

Clerical Staff

Patricia J. Crawford
 Program Assistant III

Lois A. Inlow
 Secretary II

Betty J. Metry
 Secretary I

Over

Part-Time Volunteer Faculty/Staff

- Serge Martinez, M.D.
 Division of Otolaryngology
 Welby Winstead, M.D.
 Division of Otolaryngology
 Julie Goldman, M.D.
 Division of Otolaryngology
 Toni Ganzel, M.D.
 Division of Otolaryngology
 Denise Carden, M.S.
 University Speech Pathology Associates
 Barbara Chaudoin, M.S.
 Louisville Deaf Oral School
 Rebecca Dausman, M.S.
 Easter Seal Society
 Susan Staggs, M.S.
 Child & Youth Clinic
 Marsha Flores, M.S.
 V.A.M.C.
 Sue Windmill, M.S.
 V.A.M.C.
 Rick Lazich, M.S.
 Kentuckiana Ear, Nose & Throat, P.S.C.
 Norma Newitt, M.S.
 Humana Hospital-Audubon
 Kathy Panther, M.S.
 Frazier Rehabilitation Center
 Peter Pearlman, M.S.
 Louisville Hearing Aid Centers, Inc.
 Judy Polom, M.S.
 Louisville Deaf Oral School
 Lillian Seligman, M.S.
 V.A.M.C.
 Cynthia Smith, M.S.
 Cynthia Smith & Associates
 Ellen Somer, M.S.
 Child Evaluation Center
 Therese Boesing, M.S.
 Easter Seal Society
- JoLynn B. Drury, M.S.
 JoLynn B. Drury & Associates
 Mary Jane Enrich, M.S.
 Private Practice
 Kimberly Huber, M.S.
 Southeast Rehabilitation Center
 Mary Krebs, M.S.
 Jefferson County Public Schools
 Linda Maier, M.S.
 Easter Seal Society
 Carole Oglesby, M.S.
 University Speech Pathology Associates
 Ann Perkins, M.S.
 Oldham County Public Schools
 Beverly Schipper, M.S.
 Easter Seal Society
 Denise Weber, M.S.
 Jefferson County Public Schools
 Joyce Wooldridge, M.S.
 Commission for Handicapped Children
 Joan Dance, M.S.
 Humana Hospital-Audubon
 Clarence Denoux, M.S.
 Jefferson County Public Schools
 Jane Dyer, M.S.
 Richmond, Peisel, Richmond, P.S.C.
 Margaret Johnson, M.S.
 University Audiology Associates
 Michelle King, M.S.
 Commission for Handicapped Children
 Kimberly Cripe, M.S.
 Frazier Rehabilitation Center
 Kristi Martin, M.S.
 Jefferson County Public Schools
 Fawn Wujick, M.A.
 Kentuckiana Ear, Nose & Throat, P.S.C.
 Jenny Kemp, M.S.
 University Audiology Associates
 Vicki Edin, M.S.
 Easter Seal Society

APPENDIX D

IMPROVING EDUCATIONAL STANDARDS FOR AUDIOLOGY

POSITION STATEMENTS AMERICAN ACADEMY OF AUDIOLOGY

American Academy of Audiology: Graduate Education

Background

The American Academy of Audiology, at its formation, embraced the principle of a doctoral level entry to the practice of audiology (*Audiology Today*, 1:1988). The Academy recognized that extensive consideration was required regarding both the feasibility and the impact of such a concept on the profession of audiology. In particular, the Academy desired to examine the implications of doctoral-level entry on training programs, public and private institutions, and on those individuals presently practicing in the field.

Thus, a Task Force was appointed by President James Jerger in 1989. The Task Force was charged to study the concept of a professional doctorate in audiology and to make recommendations regarding implementation of the degree. The Task Force was requested to provide a report of its deliberations and recommendations to the Academy's Executive Committee. The members of the Task Force, Lucille Beck, Carl Binnie, Alan Feldman, Barry Freeman, Susan Jerger, Richard Talbott, Chair, and Richard Wilson, met in Houston, Texas on January 26 and 27, 1990.

In their deliberations, the Task Force: 1) considered open-ended input received directly from the membership of the Academy; 2) examined existing plans on professional doctorates acquired from other organizations; and 3) received input based on the experience and expertise of the Task Force members. The report of the Task Force was submitted to and accepted by the Executive Committee of the Academy on February 3, 1990. A writing group (Judy Gravel, Linda Hood, and Rick Talbott) synthesized the Task Force report into a Position Statement for presentation to the Membership at the Academy's Annual Meeting in New Orleans, April 1990.

Position Statement

The American Academy of Audiology endorses the doctoral degree as the appropriate minimal entry level degree for the practice of audiology. This level of training is necessary to ensure the provision of the highest standards of service delivery to individuals with auditory and other related communications disorders. The professional doctorate degree establishes the audiologist in a clearly-defined and prominent role within the health-care delivery system and supports the professional autonomy of the audiologist in the practice of audiology.

To this end, the Academy shall actively seek to influence training institutions, federal and state regulatory agencies, fiscal intermediaries, professional organizations and the general public toward the acceptance of the doctorate as the minimum degree required for the practice of audiology.

- Several basic principles are hereby adopted by the Academy to guide its advocacy in this regard, as follows:
- The Academy shall foster and seek cooperative efforts between itself and other professional organizations and academic institutions pursuant to the development of recommended programs of study for the professional doctorate. The purpose of these recommendations will be to establish academic and clinical requirements for the professional doctorate degree. Such requirements should be sufficiently flexible to facilitate individual university/college variance in the models under which doctoral level education in audiology is provided.
- The Au.D. is an appropriate designator for the professional doctorate in audiology.
- A baccalaureate degree from an accredited university/college is recommended for entrance into a professional doctorate program.
- The Academy does not endorse the grandfathering or entitlement of any degree or title.
- The Academy will actively encourage university/college programs to modify entrance requirements, provide credit for demonstrated competence in the field, and allow matriculation on a full or part-time basis for audiologists desiring to complete the professional doctorate requirements.

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POSITION STATEMENT

The American Academy of Audiology and the Professional Doctorate (Au.D.)

The issue of the professional doctorate (Au.D.) as the appropriate entry degree for audiology has been growing in importance and interest. At the 1991 Convention of the Academy, the Executive Committee appointed an ad hoc committee from the Board of Representatives consisting of Charles Berlin, James Curran, Patricia Nordsrom and Gretchen Syfert, to produce a document utilizing sections of two previously unpublished working papers, as well as other sources. James Curran and Wayne Olsen were asked to further refine the position paper in terms of style and expression without change to its content. The Board of Representatives and Executive Committee unanimously passed the final revised document. It clearly states the Academy and its membership believe in the critical need for improvement in the quality of education that future audiologist-practitioners will receive.

Introduction

The American Academy of Audiology endorses the concept of the professional doctorate in audiology as the appropriate entry-level degree for the practice of audiology^{1,2}. The advanced level of training the professional doctorate mandates is necessary to ensure the provision of the highest standards of delivery of service to individuals with auditory and other related disorders and to their families. The professional doctorate establishes audiologists in a clearly defined and prominent role within the hearing health care delivery system and strengthens their position as autonomous practitioners and providers of audiological services.³

Policy Statements

The specific purpose of the professional doctorate in audiology is to prepare highly skilled practitioners. Professional doctorate programs in audiology must significantly exceed the academic and training experiences provided by Master's level programs and provide at least four years training and education after the completion of accredited Baccalaureate work.³ Such programs must demonstrate sufficient depth and breadth to warrant the doctoral designation.⁴ An entirely different degree designation, the Au.D. (Doctor of Audiology), is necessary to describe this professional degree and to differentiate it from the research-oriented Ph.D.

The Academy shall seek to influence academic institutions, federal and state regulatory agencies, fiscal intermediaries, professional organizations and the general public towards the acceptance of the professional doctorate in audiology (Au.D.) as the preferred entry-level degree for the practice of audiology.

Guiding Principles

The focus of an academic doctorate (Ph.D.) is on research culminating in the dissertation for the Ph.D.; the focus of the professional doctorate in audiology (Au.D.) is on the development of clinical proficiency. The Ph.D. is defined as the *mark of highest achievement in preparation for creative scholarship and research, often in association with a career in teaching at a university or college*.⁵ The professional doctorate (Au.D.) is, the *highest university award given in a particular field in recognition of completion of academic preparation for professional practice and does not require a dissertation for its completion*.⁵

The primary objective of the Au.D. program is to produce audiologists who are functionally competent in providing the wide array of diagnostic, remedial and other skills and services associated with the practice of audiology. Hence, there is major emphasis on the clinical learning experience. Although the professional doctorate in audiology (Au.D.) is not a research-oriented degree, it is imperative that student practitioners be familiar with the scientific and research literature that undergirds audiology, have the knowledge and the skills requisite to evaluate and interpret the audiological and related research literature, and be able to synthesize and apply pertinent research knowledge to the problems of clinical practice.⁵

Ideally, Au.D. degree programs should be organized and implemented within sponsoring institutions, such as colleges and universities, that will provide for an



independent school and faculty and should be constituted similar in nature to the degree programs which grant doctorates in other professions, such as dentistry, medicine, optometry, veterinary medicine, etc. Traditional graduate programs are structured to grant academic doctorates rather than professional doctorates. Consequently, Au.D. programs should be administered whenever possible independent of existing graduate school programs.⁶ They should be practitioner and patient-service driven, i.e., the basic orientation of the training programs should be to facilitate the development of the highest level of audiological skills in the student-practitioner, with concomitant emphasis on delivery of superior audiological services to the patient.

Considerable responsibility falls upon the clinical and academic faculty. It must be large and diverse enough to represent to the student-practitioners the leading edge of hearing care skills and services. Didactic instruction should focus on direct application of audiological sciences to hearing care needs.⁴ The faculty and the sponsoring institution will have the ultimate responsibility to evaluate formally the student-practitioner's progress and to assess the student-practitioner's mastery of the program's content, pursuant to the awarding of the Au.D. degree.

The AAAudiology is fully aware the implementation of the professional doctorate in audiology (Au.D.) contains significant challenges and departures in audiological education, and will foster and seek cooperative effort between itself and degree granting institutions to develop programs jointly acceptable to the AAAudiology and related professional organizations.

The Clinical Training Program

The Au.D. educational process assumes development of broadly based clinical rotations based on substantive academic achievement. The preparation of the complete practitioner rests upon three essential foundations:

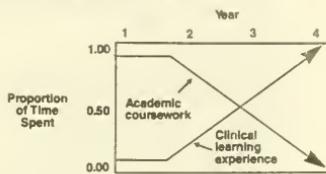
- Mastery of the audiological knowledge base (See Appendix)
- Extensive clinical experience and rotations
- Role modeling based on exposure to experienced, practicing clinicians

It is recommended that the student receive between 2500 and 3000 hours of clinical experience with an extensive variety of cases and preceptors. Student-practitioners should be exposed extensively to diverse and challenging clinical populations. Appropriate clinical training environments should include but not be limited to:

- Audiology/Medical practices
- Autonomous private practices in audiology
- Community clinics
- Hospitals

- Industrial settings
- Local education agencies
- Schools for the hearing-impaired
- University or college clinics

At least four separate rotations from the above list are recommended as a minimum as the student progresses through the program of study. The process of clinical experience should evolve in scope and complexity from limited clinical exposure with close supervision during the first years, to fourth year independent status. Whereas the first two years of the program are heavily weighed towards didactic classes and program are heavily weighted towards didactic classes and laboratory coursework, emphasis during the second two years shifts to clinical learning experiences.⁴ The proportion of clinical learning experiences as compared to academic instruction during the professional doctorate (Au.D.) program is depicted below.



Appendix

The intent of this section is to specify general areas of study which are considered essential to the knowledge base of the audiologist-practitioner.⁷ It is understood that the exact specification of curriculum and emphasis is the responsibility and propery the domain of the educational institution that offers the Au.D. degree. As in most professional degrees, a basic science core is essential. This core can be provided by basic science faculty from other departments and schools within the degree granting institution. The following general areas of study are recommended.

Basic science areas include

- Physics of sound, acoustics, psychoacoustics
- Research methods and statistics
- Speech science and perception
- Computer science
- Electronics, instrumentation and calibration
- Gross anatomy, neuroanatomy and neurophysiology
- Anatomy and physiology of hearing

Diseases and pathologies of the ear and nervous system
 Related medical diagnosis and treatment
 Embryology and genetics
 Clinical pharmacology
 Epidemiology
 Radiographic techniques and imaging

General areas of professional instruction include:

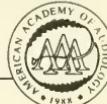
1. Audiology assessment
 - Case history/interview techniques
 - Physiologic measurements
 - Electrophysiologic measurements
 - Behavioral tests of auditory function
 - Communication measurement scales
2. Medical considerations
 - Audiologic manifestations of ear disease
 - Clinical diagnosis and evaluation of auditory pathology
 - Clinical decision analysis
3. Clinical decision process/counseling
 - Counseling strategies and techniques
 - Referral procedures and case management
 - Interprofessional relationships and responsibilities
 - Personal and interpersonal dynamics
4. Professional issues
 - Ethical/legal/quality improvement issues
 - Fiscal intermediaries/government agencies
 - Practice management/healthcare marketing
 - Forensic audiology
5. Conservation of hearing and prevention of hearing loss
 - Public and consumer education
 - Hearing conservation models
 - Identification and screening models
 - Federal/state regulations
 - Worker's compensation issues
6. Special populations
 - Pediatric audiology
 - Geriatric audiology
 - Difficult to test, including developmental disabilities
7. Audiologic habilitation and rehabilitation
 - Normative developmental models
 - Auditory training
 - Visual communication, including speech reading
 - Manual communication systems and skills
 - Speech and language of the deaf and hard of hearing
 - Educational management
8. Management of amplification
 - Physical and electroacoustic characteristics of amplifying devices
 - Methods of evaluation
 - Rehabilitative procedures
 - Dispensing
 - Assistive devices
 - Implantable devices
9. Vestibular evaluation
 - Techniques and procedures
 - Rehabilitative strategies

—Denver, April 28, 1991

References

- 1 Jager, J. *Audiology Today*, VI, #1, 1988, pp 1-14
- 2 Report on Graduate Education in Audiology, in Graduate Education in Audiology, Appendix C, American Academy of Audiology, April 24, 1990
- 3 Task Force on the Professional Doctorate, Report to Executive Committee, American Academy of Audiology, February 6, 1990
- 4 Conference on Professional Education, Proceedings of the Academy of Dispensing Audiologists, Chicago, October 9, 1988, p 15
- 5 Final Report of the Ad Hoc Committee on Doctoral Education, Council of Graduate Programs in Communication Sciences and Disorders, March 7, 1991
- 6 Goldstein, D and Benne, C, The Doctor of Audiology Degree (Au.D.) and Professional Education, Audiology Foundation of America, November, 1990, pp 8-11
- 7 Position Paper, Guidelines for Professional Doctoral Training, American Academy of Audiology, January 29, 1991.

Published in *Audiology Today*, Volume 3, No. 4, July-August, 1991



APPENDIX E

SCOPE OF PRACTICE

POSITION STATEMENT AMERICAN ACADEMY OF AUDIOLOGY

Audiology: Scope of Practice

Development of a Scope of Practice document began in 1990 with the work of an *ad hoc* committee on Scope of Practice, chaired by Alison Grimes. The document was put into final format by Robert W. Keith in 1992.

The Scope of Practice document describes the range of interests, capabilities and professional activities of audiologists. It defines audiologists as independent practitioners and provides examples of settings in which they are engaged. It is not intended to exclude participation in activities outside of those delineated in the document. The overriding principle is that members of the Academy will provide only those services for which they are adequately prepared through their academic and clinical training and their experience, and that their practice is consistent with the Academy Code of Ethics.

As a dynamic and growing profession, the field of audiology will change over time as new information is acquired. This Scope of Practice document will receive regular review for consistency with current knowledge and practice.

I. Purpose

The purpose of this document is to define the profession of audiology by its scope of practice. This document outlines those activities that are within the specialty of the profession. This Scope of Practice statement is intended to be used by audiologists, allied professionals, consumers of audiological services, and the general public. It serves as a reference for issues of service delivery, third-party reimbursement, legislation, consumer education, regulatory action, state and professional licensure and inter-professional relations. The document is not intended to be an exhaustive list of activities in which audiologists engage. Rather, it is a broad statement of professional practice. Periodic updating of any scope of practice statement is necessary as technologies and perspectives change.

II. Definition of an Audiologist

The central theme of the profession of audiology is auditory impairment and its associated communicative disorders. Audiologists are primarily concerned with the identification, evaluation, and rehabilitation of the individual with either peripheral or central auditory impairment, and with the prevention of such impairment. All professional activities related to this central theme fall within the purview of audiology. In addition, professional activities related to vestibular function fall within the competence of audiologists. An audiologist is a person who, by virtue of academic and clinical training and appropriate certification and/or licensure, is uniquely qualified to provide a comprehensive array of professional services related to the assessment and rehabilitation of persons with auditory and vestibular impairments, and to the prevention of these impairments. The audiologist serves in a number of roles: clinician, therapist, teacher, consultant, researcher and administrator.

Audiologists provide clinical and academic training to students in audiology. Audiologists teach physicians and medical students about non-medical and non-surgical aspects of hearing and hearing loss. They also provide information and training on all aspects of hearing and vestibular function and communication disorders and rehabilitation to other professionals including psychology, counseling, rehabilitation, education and other related professions. Audiologists also provide information and

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services to business and industry. Further, audiologists serve as expert witnesses within the boundaries of forensic audiology.

The audiologist is an independent practitioner, who provides services in hospitals, clinics, schools, private practices and other settings in which audiological services are relevant.

III. Scope of Practice

The scope of practice of audiologists is defined by the training and knowledge base of professionals who are licensed and certified to practice as audiologists. Areas of competence include assessment and rehabilitation of individuals with auditory and vestibular disorders, prevention of hearing loss, and research in normal and disordered auditory and vestibular function. The practice of audiology includes:

A. Assessment

Specifically, assessment of hearing includes the administration and interpretation of behavioral, electroacoustic, and electrophysiologic measures of the peripheral and central auditory systems. Assessment of the vestibular system includes administration and interpretation of clinical and electrophysiologic tests of equilibrium. Assessment is accomplished using standardized testing procedures and appropriately calibrated instrumentation.

B. Rehabilitation

The audiologist is the professional who provides the full range of rehabilitative services for persons with hearing impairment. The audiologist is responsible for the evaluation and fitting of all types of amplification devices, including hearing aids and assistive listening

devices. The audiologist determines the appropriateness of amplification systems for persons with hearing impairment, evaluates their benefit, and provides counseling regarding their use. Audiologists conduct otoscopic examinations, clean ear canals, take ear impressions, fit and dispense hearing aids and other amplification systems.

Audiologists are also involved in the rehabilitation of persons with vestibular disorders. They may participate as full members of vestibular rehabilitation teams to recommend and carry out goals of vestibular rehabilitation therapy including, for example, habituation exercises, balance retraining exercises, and general conditioning exercises.

The audiologist is the member of the cochlear implant team who determines candidacy based on auditory and communication information. The audiologist provides pre- and post-surgical assessment, counseling, auditory training, rehabilitation, implant programming, and maintenance of implant hardware.

The audiologist provides rehabilitation to persons with hearing impairment, and is a source of information for family members, other professionals and the general public. Counseling regarding hearing loss, the use of hearing prosthetic devices and strategies for improving speech recognition is within the expertise of the audiologist. Additionally, the audiologist provides counseling regarding the effects of hearing loss on communication and psychosocial status in personal, social and vocational arenas.

The audiologist administers services to students of all ages with hearing impairment from pre-school through high school, including identification, evaluation and rehabilitation. The audiologist is an integral part of the team within

the school system which manages hearing impaired students and students with central auditory processing disorders. The audiologist serves as the resource for school personnel in the development of Individualized Educational Programs (IEP's) and in matters pertaining to classroom acoustics, assistive listening systems, hearing aids and communication, and maintains both classroom assistive systems as well as student's personal hearing aids. The audiologist administers hearing screening programs in schools, and trains and supervises non-audiologists performing hearing screening in the educational setting.

C. Hearing Conservation

The audiologist designs, implements and coordinates industrial and community hearing conservation programs. This includes identification and amelioration of noise-hazardous conditions, identification of hearing loss, recommendation and counseling for use of hearing protection, employee education, and the training and supervision of non-audiologists performing hearing screening in the industrial setting.

D. Research

The audiologist is one of the professionals

responsible for the design, implementation, analysis, interpretation, and administration of research related to the auditory and vestibular systems.

E. Additional Expertise

Some audiologists, by virtue of education, experience and personal choice, choose to specialize in a particular specialty area of practice and thereby confine their skills, knowledge and practice to that specialty. Further, some audiologists, by virtue of education, experience and personal choice, engage in activities outside of those defined in this scope of practice. Nothing in this document shall be construed to limit individual freedom of choice in this regard provided that the activity is consistent with the American Academy of Audiology Code of Ethics.

This document will be reviewed, revised and updated periodically in order to reflect changing clinical demands of audiologists and in order to keep pace with the changing scope of practice reflected by these changes and innovations in this specialty.

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* 1992 Executive Committee

September 13, 1993

The Honorable David Pryor
Chairman, Senate Special Committee on Aging
SR-267 Russell Senate Office Building
Washington, DC 20510-0402

Dear Senator Pryor:

The Hearing Industries Association (HIA) represents 31 companies that manufacture and distribute hearing aids, hearing aid components, accessories and hearing health care products in the United States. As the representative of the companies that produce over 80 percent of the hearing aids sold in the US, HIA appreciates the opportunity to submit this statement for inclusion in the record of the September 15, 1993 hearing on hearing aids before the Senate Special Committee on Aging.

HIA agrees with the need identified by the Committee to examine periodically the role of hearing aids from a public health perspective. Importantly, hearing loss is the third most prevalent chronic condition affecting older Americans. While estimates vary and most are understated, as they are based only on self-reported hearing losses, the National Center for Health Statistics estimates that there are approximately 28 million individuals in the US with a degree of hearing loss; we know that the vast majority of those individuals are over age 50.

While hearing loss is not exclusively a function of the aging process, it is a common partner. Yet, for a variety of reasons, most individuals over the age of 50 years, and even those who suspect that their hearing is a problem, have not had a complete evaluation of their hearing. Of those with identified hearing problems, three-quarters do not yet benefit from the only assistance available, hearing aids.

Hearing aids do not cure hearing loss. Treatment, either medical or surgical, may alleviate some hearing losses or even provide a cure for at most an estimated 10 percent of individuals with hearing loss. For many of the rest, hearing aids can and do provide a significant benefit and, indeed, amplification is the only assistance available to provide hearing help in communicative situations.

As the American population ages, therefore, we think it is quite appropriate to examine the issues surrounding the sale and use of hearing aids in this larger context. We are of the view that our industry has much to contribute to the general health, well-being and independent functioning of people with hearing losses. We take our manufacturing, marketing, and research activities very seriously in light of the importance of our products.

When we look in perspective at the public health dimensions of hearing loss, one must be struck by a few observations...

First, the vast majority of adults in this country with hearing loss have never received a complete hearing evaluation and do not benefit from using amplification or corrective devices. In a study conducted in the early 1980s, HIA found that 68% of individuals with hearing losses received no recommendation about further testing or treatment or they received a negative recommendation against using hearing aids from their physicians.

This finding, coupled with other studies that revealed the critical role that a physician recommendation plays in an individual's decision to seek hearing health help, resulted in information efforts by the hearing aid industry. Over the past decade, HIA has conducted professional seminars at the annual meetings of the American Academy of Family Physicians (AAFP) and family physicians' state-level society meetings. Further, HIA funded the production of a video course about hearing loss and hearing aids developed by the Maryland Academy of Family Physicians and endorsed by the AAFP for Continuing Medical Education. Additionally, HIA implemented a generic informational advertising campaign encouraging physicians to screen hearing electronically on a routine basis; these ads are running in publications such as *Patient Care* and *Postgraduate Medicine* and they offer an HIA publication, "The Physician's Guide to Hearing Loss." Another study has confirmed that these and other efforts resulted in increasing the percentage of physical examinations that include a preliminary hearing screening from 16% to almost 21%, but that still indicates that three-fourths of adults will not even receive a screening test.

Research indicates that individuals are reticent to identify a hearing problem for a number of reasons. Hearing loss is usually painless and gradual in its onset and development, allowing individuals to function adequately with certain degrees of adaptation in the early stages. Additionally, data confirms that people associate hearing loss with aging, a process that is denied and delayed to all possible extent in our youth-oriented society.

Further, many people do not regard hearing loss as a serious problem. In fact, it is a problem, and we would strongly urge your committee to underscore this fact. Hearing loss can cause people to become isolated and detached. It can cause them to perform less efficiently at work and to lose contact with family activities. In the extreme, uncorrected hearing loss can cause people to become depressed and even suicidal. The companies that make hearing aids and related products view hearing loss as a health issue that must receive higher priority in the United States and we urge the Committee to help underscore its importance.

Second, the majority of hearing aid purchasers and users are satisfied with their hearing aids. One of the major investigations of consumer satisfaction with hearing aids, the MarkeTrak research, has demonstrated that the majority of consumers are generally satisfied with hearing aids and believe that their quality of life is enhanced by hearing aid use.

HIA published a special report on this research and it is provided with this letter as Attachment I. The key findings of this research, in addition to general satisfaction with hearing aids by users, are: almost 80 percent of satisfied users would recommend hearing aid use to their friends; consumers are very satisfied with the services of their hearing aid dispensers; and two out of three of them would repurchase their current brand of hearing aid.

The quality of life findings reported in MarkeTrak are also reflected in numerous research findings. Of particular importance is one study that was reported in the August 1990 issue of the *Annals of Internal Medicine*. This article, provided with this letter as Attachment II, concludes that, "Hearing loss is associated with important adverse effects on the quality of life of elderly persons, effects which are reversible with hearing aids."

Third, but related to the previous point, HIA believes that the actual hearing aid users' satisfaction rate is even higher than current studies show, due to the fact that the studies fail to distinguish between satisfaction and benefit. No one wants to wear a hearing aid as, like any prosthetic device, the hearing aid can only help compensate but cannot replace the lost hearing ability. Consequently, the user will view the device as an unwanted necessity, and it is fundamentally wrong to apply standard measures of consumer satisfaction to this type of product.

HIA believes that benefit levels, as opposed to satisfaction levels, are quite high. Individuals will report an ability to hear better, to understand speech better, to listen with less effort when using their hearing aids. However, even with these benefits, they may continue to report less than 100 percent satisfaction, as again the hearing aid cannot restore or replace abilities that have been lost. The inherent technological limitation of a hearing aid and the desire of all individuals to maintain maximum function may result in unmet expectations that are incorrectly viewed as dissatisfaction with the hearing aid.

Fourth, the hearing aid industry is well aware of and fully understands the advertising issues raised by the Food and Drug Administration (FDA). As you know, a number of manufacturers have received letters from FDA raising questions about claims made in advertising, and these companies are cooperating fully with the agency. Further, let me assure you that all members of HIA are seeking to comply fully with FDA's concerns, and they are working to ensure that advertising now appearing is responsive, to the degree possible, to the FDA's stated concerns.

We would hope that your hearing focuses on the high degree of compliance by our industry in responding to FDA rather than on FDA's perception of previous offenses. To dwell on the FDA's past actions would mislead the public into believing that the hearing aid industry is unresponsive and irresponsible.

At the same time, HIA believe that there are claims, beyond the ones authorized by FDA, that can be made for hearing aids, particularly claims that deal with enhancement of quality of life. We have opened a constructive dialogue with FDA to seek to identify additional claims that can be made. If further studies are required to document such claims, they will be undertaken.

Fifth, we believe that the public is well-protected in the present system by which hearing aids are purchased. Manufacturers of hearing aids provide, at a minimum, a full one-year warranty that covers all standard features and usually includes even loss and damage coverage for the hearing aid. Additionally, all manufacturers provide dispensers with at least a 30-day return policy. Studies of dispensing practices reflect that most dispensers, in turn, extend this privilege to their consumers. This means that purchasers of hearing aids, most of which are custom-made to fit that specific individual, can return their hearing aids within the appropriate time frame if dissatisfied for any reason and receive a refund. HIA knows of no other custom-made products for which there is this type of consumer satisfaction guarantee.

Indeed, the industry recognizes that some degree of the only 5-6 percent refund rate of hearing aids is due to unrealistic expectations of the hearing aid's performance. However, given the significant underutilization of amplification, it is important that hearing aid manufacturers and dispensers be able to maintain positive and truthful advertising and promotional messages. It would be a great disservice to the public to discourage visits to hearing health care providers.

Consumers over age 18 have the option to secure a medical examination if they choose or to waive this requirement if they elect to do so. This system has worked well to provide consumers with appropriate options in pursuing the purchase of a hearing aid. We understand that FDA intends to change this waiver provision, and we will comment on the proposed changes as appropriate. HIA does not see a compelling need for change in the present system, which we believe is serving consumers well. If companies or dispensers are not complying with the FDA's regulations, the agency should enforce its rules. However, changing the regulation because consumers accept the lawfully available waiver is wrong, and contrary to consumer interests.

We are all well aware that there are anecdotes about people who feel that the current system of purchasing has not worked well for them. Let me assure you that for every anecdote that raises questions about hearing aids, there are many, many more that could be obtained from satisfied users. Anecdotes may make for entertaining television and media-appealing sound-bites. But they do not provide the basis for any broad conclusions that there are abuses in the system, or that consumers are generally dissatisfied. In fact, HIA and others regularly conduct objective, statistically-based surveys to detect any trends toward dissatisfaction, and we find no evidence that the public is uncomfortable with the present system.

We would urge, therefore, that as your Committee examines issues about hearing aids, you not be swayed by anecdotal experiences, but rather by sound and objective public opinion research. It would be a great disservice to the public to be led to believe, based on individual anecdotes, that the purchase and dispensing of hearing aids poses a serious problem.

Finally, HIA believes that concerns about prices are ill-founded. Hearing aid prices reflect more than just the cost of raw materials and their assembly. As with other advanced technologies, the cost also reflects the research and development costs as well as the meticulous quality control involved in the manufacturing process. Further, the cost of hearing aids in comparison to other technologies must be viewed in terms of the relatively small number of hearing aids that are produced on an annual basis. Additionally, hearing aid costs also reflect an additional unique feature; the vast majority of hearing aids are custom-made, fitted exactly to the ear of the prospective user.

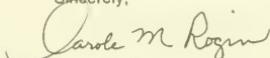
Hearing aids provide good value. They improve hearing. They improve quality of life. It is difficult to place a price on this benefit, but it is certainly one that must be taken into account in determining good value.

In sum, we agree with your Committee that appropriate focus should be placed on hearing aids. HIA believes that the public health mandates are clear for more Americans to have hearing loss diagnosed; to remove the stigma associated with hearing loss and hearing aids; to educate more Americans about the latest technology; to assure that every consumer understands his or her rights and options; and to examine closely the scientific evidence behind our products and behind the current system of access.

The aging of America's population means that more people will want and need hearing aids. They will want and need hearing aids that are advanced technologically but that are also affordable. We believe our industry has met the challenges of the past and is poised to meet those of the future.

We remain available to work with you as you continue to explore these important issues.

Sincerely,



Carole M. Rogin
President

Attachments (2)

The Marketing Edge

Published by the Hearing Industries Association ■ 515 King Street, Suite 320, Alexandria, VA 22314

Special Issue June 1993

Consumer Satisfaction with Hearing Instruments in the United States

Sergei Kochkin, Ph.D.
Knowles Electronics, Inc.

Introduction

A number of studies have sought to access consumer perceptions of hearing aids. This paper reports on a survey taken in 1984 and on research conducted by Knowles Electronics in 1991.

Overall, consumers give high marks to hearing aids. They feel that they generally are satisfied with hearing aids and that their quality of life is enhanced by hearing aid use.

FTC Study

The most recent government sponsored study in the U.S. on consumer satisfaction with hearing instruments was conducted on behalf of the Federal Trade Commission (FTC) in 1984 by Market Facts, a market research firm. The FTC study was conducted among 847 hearing instrument owners who reported their hearing instruments were two years or less in age. Responses were confined to respondents who held specific beliefs about what the hearing instrument was capable of.

The ratings given by this sub-population of hearing instrument owners were outstanding:

- 84% indicated they were very satisfied or somewhat satisfied with the ability to hear with the hearing instrument; only 10% were dissatisfied with the hearing instrument.
- 76% indicated they would return to the dispenser to purchase their next hearing instrument.

Biography

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- 95% indicated the instrument made it possible (somewhat/definitely) to understand normal conversation.
- 94% said it improved (somewhat/definitely) their hearing.
- 82% said it helped them distinguish sounds and voices in crowds (somewhat/definitely).
- 79% said it restored their hearing (somewhat/definitely).

Knowles/NFO Research

In October 1991, a short screening survey was mailed to 80,000 members of the National Family Opinion Panel (NFO). The NFO panel consists of households that are balanced to the latest U.S. census information with respect to market size, age of household, size of household and income within each of the nine census regions, as well as by family versus non-family households, state (with the exception of Hawaii and Alaska), and the nation's 25 largest metropolitan statistical areas.

This screening survey helped identify more than 13,000 households with at least one person indicating a hearing difficulty. In December 1991, extensive surveys were sent to 3,000 hearing instrument owners and 3,000 non-owners with a hearing difficulty. The data for this paper is based on usable survey returns from 2,323 hearing instrument owners.

This study asked respondents to indicate the impact the product had on their quality of life and whether or not they would recommend hearing instruments to friends, repurchase their

current brand, return to their dispenser and the extent to which the product was worn. In addition, using a "very satisfied, satisfied, neutral, dissatisfied, very dissatisfied" scale, respondents rated hearing instruments on 42 factors.

The table documents 46 measures of consumer satisfaction with hearing instruments in the U.S. market. In addition, the last column in the table shows the ratio between satisfied consumers and dissatisfied consumers.

Overall Satisfaction

58% of current hearing instrument owners reported that overall they are satisfied or very satisfied with their hearing instrument; 20% report they are dissatisfied. Satisfaction ratings are however significantly related to the age of the hearing instrument (data not shown). Owners with one year old hearing instruments report a 66% satisfaction rating and a 12% dissatisfaction rating. This can be compared to 5 year old hearing instruments (56% satisfied/19% dissatisfied) and 10 year old hearing instruments (48% satisfied, 29% dissatisfied).

Consumer Experiences

Similar to the 1984 FTC study, the industry received high marks as evidenced by the following consumer attitudes/behaviors:

- Nearly 8 out of 10 owners would recommend a hearing instrument to a friend with a hearing loss.
 - Approximately 7 out of 10 owners would recommend a specific dispenser.
 - Two out of three consumers would repurchase their current brand.
 - 65% report that hearing instruments have significantly improved the quality of their life, less than 7% report their hearing instrument has not improved the quality of their life.
 - 12% of owners never use their hearing instruments.
- Comparing the extremes of satisfaction (very satisfied, very dissatisfied—analysis and data not shown), the very satisfied individual is:
- 12 times more likely to repurchase their current brand.

- nearly 4 times more likely to generically endorse hearing instruments.
- nearly 7 times more likely to recommend the dispenser who fit their hearing instrument.

Satisfaction with Hearing Instruments

Consumer satisfaction with ten hearing instrument product features and nine performance/value factors are next shown in the attached table. With respect to product features, nearly 8 out of 10 consumers report satisfaction with fit and comfort of the hearing instrument, less than 8% report dissatisfaction. Similarly high ratings were received for hearing instrument size, appearance, visibility and ease of volume adjustment. Product features receiving ratings in the 60% range include: packaging, frequency of cleaning, warranty, and ease of battery change. The lowest rated product feature was on-going expense (49%).

With respect to product performance, nearly 9 out of 10 consumers are satisfied with battery life and 7 out of 10 with product reliability. Nearly 3 out of 4 consumers report satisfaction with the ability of the hearing instrument to improve their hearing while only 11% report dissatisfaction. Approximately half of the owners believe that sound quality and the ability to localize direction are satisfactory. The most severe ratings are given to whistling/feedback/buzzing (38% satisfaction/33% dissatisfaction) and the ability to use the hearing instrument in noisy situations (28% satisfaction/47% dissatisfaction). Noteworthy is the perception by only slightly more than half of the respondents that hearing instruments have satisfactory value. In the survey, we specifically defined the term value for the consumer as "performance versus money spent".

Satisfaction in Listening Environments

Consumers were asked to rate their level of satisfaction in 11 listening situations from one-on-one communication to large groups. Nearly 9 out of 10 owners report satisfaction with hearing instruments in one-on-one communication and 7 out of 10 while watching TV. However, satisfaction ratings decline dramatically as a function of the complexity (noisiness) of the

listening environment with large group environments receiving the lowest ratings (25% satisfaction/49% dissatisfaction). A device that improves hearing in limited situations is predicted to result in lower satisfaction ratings, lower repurchase rates, and more negative "word-of-mouth" advertising. In a more detailed segmentation analysis of our data, we have found strong associations between satisfaction and the variety of listening environments in which the consumer's hearing was improved. Considering the segment of consumers who experience improved hearing in no listening environment (8.8% of owners), they report an overall satisfaction rating of only 6%. This should be compared to the 13.6% of owners reporting satisfaction in all 10 rated listening situations; their satisfaction rating was 91.5%. Forty percent of the current hearing instrument owner market report satisfaction in 70% of the listening environments measured in this study. Their combined overall satisfaction rating is 86%. Clearly this industry has the technology and the skill to achieve 80-90% satisfaction ratings.

Satisfaction with Dispenser Service

Consumer satisfaction with twelve measures of dispenser service are next shown in the attached table. The ratings given to dispensers are outstanding. All but two of the ratings are close to 90% satisfaction ratings. Nearly 8 out of 10 consumers are satisfied with the dispenser's explanation of what to expect from hearing instruments and post-purchase service. Less than 7% of consumers are dissatisfied with the dispenser's explanation of what to expect from hearing instruments. One can infer that dispensers are, in general, providing realistic expectations to consumers.

Conclusions

This study, using more stringent measures than the previous U.S. study conducted on behalf of the FTC, demonstrates that the industry, its product, and the dispenser receive high ratings as reflected by likelihood of repurchase, returning to the dispenser and endorsing hearing instruments to friends and relatives. Less than 7% of owners indicate the product has not improved their quality of life. Roughly 6 out of 10 consumers report overall satisfaction with the hearing instrument compared to 2 out of 10 dissatisfied. However, dissatisfaction ratings for newer products are more in agreement with the 1984 FTC study.

The data clearly show where the hearing aid industry is doing a good job in satisfying hearing instrument owners and where it could improve. Areas needing improvement from the consumers' perspective (based on the correlation between the overall rating and detailed ratings) are: perceived value, product reliability, the variety of listening environments in which their hearing instruments improve hearing, sound quality and on-going expense.

It would be useful to compare hearing instrument satisfaction ratings to other relevant products or services outside of the industry. Recent research on consumer perceptions of value for various services and products were published by the Conference Board (October, 1992). Using a "good", "average", "poor" value scale, the following ratings were achieved: Doctor's fees (9.5% good value/46.5% poor value), dentist fees (9.5% good/43.2% poor), prescription drugs (21.7% good/39.1% poor), eyeglasses (19.4% good/27.8% poor), contact lenses (14.4% good/27.4% poor), lawyer's fees (4.6% good/59.8% poor), and hospital charges (4.8% good/64.6% poor). While the results are not directly comparable because of the different measurement scales, in the Knowles study, 52% of hearing instrument owners indicated that they were satisfied with the value they received from their instrument; 22% were dissatisfied with the value. Hearing instruments receive more than twice as many "good value (satisfied)" ratings as "poor value (dissatisfied)" ratings. This finding should be compared to the measurements taken by the Conference Board, where "poor value" ratings consistently exceed "good value" ratings sometimes by a factor as high as 13 negatives per positive response (e.g. hospital fees).

The 1984 FTC study and the 1991 Knowles Electronics study indicate a high level of satisfaction with hearing aids. The surveys also indicate that consumers feel hearing aids improve their quality of life.

The surveys identify a number of areas in which satisfaction can be enhanced. Compared to consumer satisfaction with other products, the hearing aid industry seems to be doing very well in meeting consumer expectations and providing products that satisfies its customers.

U.S. Hearing Instrument Satisfaction Ratings (1991)

	% Very Dissatisfied	% Dissatisfied	% Total Dissatisfied	% Neutral	% Total Satisfied	% Satisfied	% Very Satisfied	Satisfied per Dissatisfied
Overall Satisfaction	7	13	20	22	58	38	20	2.8
Consumer Behavior								
Quality Of Life (Note 1)		7	28	65	41	24	64	
Recommend Hearing Aids To Friend (Note 2)	7	14	21	79			11.9	
Recommend Person Who Fit Hearing Aid (Note 2)	15	16	69				4.5	
Repurchase Current Brand Of Hearing Aid (Note 3)	33		67				2.0	
Product Features								
Fit/Comfort	2	6	8	13	80	47	32	10.5
Size	1	6	7	77	20	2	11	
Appearance	1	4	5	39	77	52	25	15.3
Ease/ Volume Adjustment	3	7	9	16	75	50	27	8.3
Visibility	1	4	6	24	71	47	24	12.6
Packaging	1	2	3	32	64	47	17	19.5
Frequency of Cleaning	2	6	8	29	63	49	14	8.3
Warranty	4	8	12	28	61	43	18	5.0
Ease/Battery Change	4	16	20	21	59	40	19	3.0
On-Going Expense	6	13	18	33	49	35	13	2.7
Performance/Value Factors								
Battery Life	0	4	4	10	86	48	38	21.5
Improves My Hearing	3	8	11	15	74	44	30	6.8
Reliability	3	6	8	20	71	46	23	8.5
Cleanliness/Tone/Sound	5	13	17	24	59	43	17	3.5
Natural Sound	5	12	17	30	53	39	14	3.1
Value (Price vs. Performance)	8	14	22	26	52	36	17	2.4
Directionality	5	15	20	31	49	38	11	2.4
Whistling/Feedback/Buzzing	9	24	33	30	38	26	9	1.1
Use In Noisy Situations	16	31	47	25	28	21	8	0.6
Listening Environments								
One-On-One	1	3	4	8	88	50	38	22.6
T.V.	3	8	12	19	69	51	19	5.9
Small Groups	3	13	16	21	64	48	15	4.0
Church	5	13	17	29	54	41	13	3.2
Outdoors	4	14	18	29	53	41	12	2.9
Bar	5	16	21	26	51	40	11	2.8
Restaurant	7	22	28	29	43	34	9	1.5
Concert/Movie	9	19	28	30	42	33	9	1.5
Telephone	13	23	36	28	36	27	9	1.0
Large Group	14	34	49	27	25	20	5	0.5
Dispenser Service								
Friendliness/Dispenser	0	1	1	7	91	42	49	76.2
Appearance/Office	0	1	1	8	91	41	50	90.9
Patience/Dispenser	0	1	2	9	59	42	37	49.7
Explained How To Use H.I.	0	2	2	9	89	46	43	37.0
Explained Purpose Hearing Test	0	1	2	10	89	44	44	52.1
Professionalism/Dispenser	0	2	2	10	87	45	45	36.4
Amount Time Spent W/Consumer	1	2	2	10	87	45	42	38.0
Follow-up	0	2	2	11	82	41	46	48.2
Explained Results Hearing Test	1	2	3	10	87	45	42	33.5
Explained How To Care For H.I.	0	3	3	11	86	46	40	29.7
Explained What to expect from H.I.	1	5	7	14	80	43	36	12.2
Post-Purchase Service	3	5	8	14	79	36	42	(0.2)

Note: All percents rounded to whole numbers.

Note 1: Dissatisfied=Never; Neutral=Some of the Time; Satisfied=Most of the Time; Very Satisfied=Always

Note 2: Dissatisfied=No; Neutral=Not Sure; Satisfied=Yes

Note 3: Dissatisfied=No; Satisfied=Yes

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Quality-of-Life Changes and Hearing Impairment

A Randomized Trial

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Objective: To assess whether hearing aids improve the quality of life of elderly persons with hearing loss.

Setting: Primary care clinics at a Bureau of Veterans Affairs hospital.

Patients: One hundred and ninety-four elderly veterans who were identified as being hearing impaired from a screening survey involving 771 consecutive clinic patients. Of the original 194, 188 (97%) completed the trial.

Intervention: Subjects were randomly assigned to either receive a hearing aid ($n = 95$) or join a waiting list ($n = 99$).

Main Endpoints: A comprehensive battery of disease-specific and generic quality-of-life measures were administered at baseline, 6 weeks, and 4 months.

Measurements and Main Results: Persons assigned to the two groups were similar in age, ethnicity, education, marital status, occupation, and comorbid diseases. At baseline, 82% of subjects reported adverse effects on quality of life due to hearing impairment, and 24% were depressed. At follow-up, a significant change in score improvements for social and emotional function (34.0; 95% CI, 27.3 to 40.8; $P < 0.0001$), communication function (24.2; CI, 17.2 to 31.2; $P < 0.0001$), cognitive function (0.28; CI, 0.08 to 0.48; $P = 0.008$), and depression (0.80; CI, 0.09 to 1.51; $P = 0.03$) was seen in subjects who received hearing aids compared with those assigned to the waiting list. Six drop-outs (three per group), no crossovers, and no significant changes in coinventions were seen. Average, self-reported, daily aid use in the hearing aid group was 8 hours.

Conclusion: Hearing loss is associated with important adverse effects on the quality of life of elderly persons, effects which are reversible with hearing aids.

Hearing impairment is one of the most common chronic health problems among elderly Americans (1-3). In 1980, over 18 million elderly persons suffered from some form of hearing loss, and this number will approach 25 million in the next decade (4-6). Approximately 25% of persons over 65 years of age report problems with their hearing, and audiologically detectable hearing loss is present in more than one third of persons over 65 years of age (7-9).

Hearing impairment can have a profoundly negative influence on the lives of elderly persons. Reported associated functional disability is considerable and common. Adverse effects on physical, cognitive, emotional, behavioral, and social function have been reported (1, 10-37). These effects are often regarded by the hearing impaired person as representing severe handicap even when the degree of audiologically detectable hearing loss is relatively mild (34, 35).

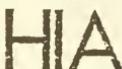
Even though hearing impairment is one of the most prevalent chronic conditions experienced by elderly persons and attendant adverse effects on ability to function are major, health care providers often fail to screen patients for hearing loss or refer affected persons for rehabilitative therapy with hearing aids. For example, in a recent survey of primary care physicians, 80% of the responding physicians stated that they did not routinely screen for hearing impairment in elderly patients (38). Only 25% of persons with hearing loss actually receive hearing aids (39), and over half of the persons who have discussed their hearing problem with health care providers are told that their hearing loss is minor or that it cannot be improved with a hearing aid (40).

We conducted a randomized controlled trial to evaluate the actual benefits of hearing aids for elderly persons with hearing impairment. Specific questions were whether hearing aids improve quality of life in elderly persons with hearing loss, which areas of quality of life are most likely to improve with hearing aids, and which instruments are most appropriate for assessing quality-of-life-associated benefits of hearing aids in elderly persons with hearing loss.

Methods

Our study was approved by the University of Texas Health Science Center Institutional Review Board. Most study subjects were recruited from the General Medicine Clinic at the Audie L. Murphy Memorial Veterans Hospital in San Antonio. The following sequential selection process was used (Figure 1). The medical records of all 771 subjects over 64 years of age who attended the General Medicine Clinic between June 1987 and June 1988 were reviewed. To maximize the ability to

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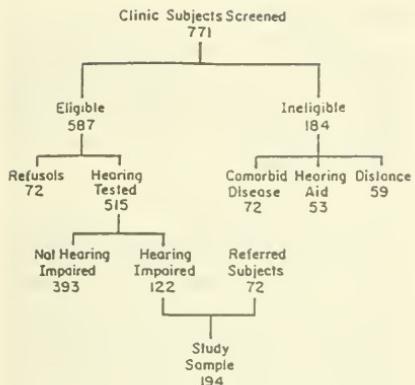


Figure 1. Subject recruitment schematic.

measure dysfunction secondary to hearing loss, 72 subjects with severely disabling comorbid diseases (terminal cancer, hepatic encephalopathy, end-stage pulmonary disease requiring home oxygen therapy) and 53 subjects who were current hearing aid users were excluded. Because of planned follow-up visits, 59 subjects living more than 100 miles from the clinic were excluded. The remaining 587 elderly patients attending the clinic were asked to participate in this study; 72 (12%) refused. (The most common reasons for refusal were insufficient time on the part of the patient [72%] and lack of interest [28%]. Persons refusing to participate were less likely to be married [61% compared with 80%, $P = 0.003$] and were older [75 ± 8 compared with 72 ± 6 years of age, $P = 0.001$] than participants.) Of the 515 clinic patients who agreed to be screened for hearing impairment, 393 were identified as non-hearing impaired and 122 as hearing impaired. In addition to these 122 hearing-impaired patients, 72 patients referred from other primary care clinics (including walk-in and nurse-practitioners' clinics) participated in our trial, for a total study sample of 194. The 72 referred subjects were patients with hearing impairment who were specifically referred by their health care providers to be considered for participation in our trial. Their demographic and clinical characteristics including degree of hearing loss were not statistically significantly different from those of the 122 patients recruited from the medicine clinic.

Definition of Hearing Impairment

Hearing impairment was initially screened for using the Welch Allyn audioscope (Welch Allyn Inc., Skaneateles Falls, New York), a hand-held otoscope with a built-in audiometer that delivers a 40-dB tone at frequencies of 500, 1000, 2000, and 4000 Hz (41-43). For the screening examination, hearing impairment was defined as a better-ear threshold of 40 dB or greater at a single frequency of 2000 Hz. This definition excludes patients with very minor degrees of hearing loss and was chosen to ensure that persons who failed screening would be reasonable candidates for hearing aids.

All persons meeting the screening definition of hearing impairment had their hearing loss confirmed within 1 week of screening with formal audiologic testing by an audiologist using a standard protocol (44). At this examination, high-frequency pure-tone average hearing (HTPA) was determined by averaging the dB loss at three frequencies: 1000, 2000, and 4000 Hz (45).

Trial Regimen

After giving informed consent to participate in a randomized trial that would evaluate the effects of hearing aids on their

ability to function and randomly assign them to either a waiting list group or an immediate hearing aid group, study subjects received baseline demographic, clinical (including near visual acuity examinations [46]), and quality-of-life evaluations. After receiving the formal audiology examination described above, they were randomly assigned in blocks of six (by calling a central study site number) to either a hearing aid group ($n = 95$) or a waiting list group ($n = 99$). Subjects assigned to the hearing aid group ordered their hearing aids immediately. Hearing aids were provided at no cost. Within 2 weeks, these subjects received a single 45-minute hearing aid fitting and orientation session; no further aural rehabilitation sessions were given throughout the trial. Both groups of subjects received follow-up quality-of-life evaluations at 6 weeks and at 4 months. After 4 months, waiting list subjects received hearing aids. (Normal waiting times for hearing aids at Audie L. Murphy Veterans Hospital are longer than 4 months.)

Baseline and Follow-up Measures

Quality of life was defined as a multidimensional concept encompassing social, affective, cognitive, and physical domains. Quality of life was assessed at baseline and follow-up using a battery of two disease-specific and three generic instruments. The disease-specific measures were the Hearing Handicap Inventory for the Elderly (HHIE), a 25-item questionnaire (scored from 0 to 100) that assesses emotional and social effects of hearing loss (47-50); and the Quantified Denver Scale of Communication Function (QDS), a 25-item questionnaire (scored from 0 to 100) that assesses perceived communication difficulties due to hearing loss (51, 52). Generic measures included the Short Portable Mental Status Questionnaire (SPMSQ), a 10-item scale (scored from 0 to 10) that assesses cognitive function (53); the Geriatric Depression Scale (GDS), a 15-item scale (scored from 0 to 15) that assesses affect (54-57); and the Self-Evaluation of Life Function (SELF), a 54-item global scale (scored from 54 to 216) that assesses six areas of functioning: physical disability, social satisfaction, symptoms of aging, depression, self-esteem, and personal control (58). For all the scales, higher scores indicate greater dysfunction. All of the scales were self-administered, except the SPMSQ which was administered by a trained interviewer. All were given at baseline and at the 4-month follow-up visit, but only a subset of the scales (HHIE, QDS) were given at the interim 6-week visit.

At 6 weeks, subjects as well as their families were asked to state whether the subject's overall social and communication function had improved, not changed, or deteriorated since the baseline evaluation. Subjects in the hearing aid group and their families were also given an 11-item questionnaire to rate their satisfaction (score range, 11 to 55; < 17 = very satisfied, > 27 = not satisfied) with the hearing aid (59).

Compliance, Crossovers, Drop-outs, and Countermeasures

Compliance was measured at 6 weeks and at 4 months by self-reported hours of hearing aid use per day. It was corroborated by counting the number of hearing aid batteries dispensed and by family reports of hearing aid use. At follow-up visits, subjects assigned to the waiting list were asked to report whether they had received a hearing aid from any other source (crossover) during the study protocol. Subjects who failed to complete either one of the two follow-up functional status evaluations for any reason were classified as drop-outs. At the end of the trial, medical records and computerized pharmacy records were abstracted to determine changes in numbers of comorbid diseases and medications, numbers of outpatient clinic visits, and numbers of hospitalizations that occurred during the trial. These assessments for potential countermeasures were made by a person who was unaware of whether the subject was assigned to the hearing aid or waiting list group.

Statistical Analysis

Statistical analyses were done using SAS (SAS Institute, Inc., Cary, North Carolina) (60). Descriptive statistics were

Table 1. Baseline Demographic and Clinical Characteristics of Persons Assigned to the Hearing Aid and Waiting List Groups*

Characteristics	Hearing Aid Group (n = 95)	Waiting List Group (n = 99)
Age, y	73 ± 7	71 ± 5
Men, %	100	99
White, %	98	96
Married, %	85	74
Education, y	9 ± 4	10 ± 4
Retired, %	93	95
Comorbid disease, n	1.3 ± 1.2	1.4 ± 1.2
Medications, n	3.1 ± 2.8	3.3 ± 2.9
Intact vision, %†	80	77
High-frequency pure-tone average, n‡	53 ± 10	51 ± 8

* Where appropriate, values are mean ± SD.

† Near visual acuity is 20/40 or better in the better eye.

‡ High-frequency pure-tone average in the better ear at 1000, 2000, and 4000 Hz.

computed for simple baseline comparisons between persons assigned to the hearing aid group and those assigned to the waiting list group. *T*-tests (61) were used to test for differences between groups in the quality-of-life change scores assessed at baseline and at the 4-month follow-up. Repeated measures analyses of variance (62) were also used to test for differences between groups in the quality-of-life measures (HHIE, QDS) that were assessed at baseline, 6 weeks, and 4 months. Chi-square tests (63) were used to compare differences in proportions between family and subject reports of overall improvement.

Analyses were initially conducted using all subjects who completed the trial. Two additional analyses were done: one using only the 122 subjects who were screened from the medicine clinic (excluding the 72 subjects referred from other clinics) and the other excluding any subjects with potential confounders that could have affected quality-of-life outcomes. As these latter two analyses showed essentially the same results as the initial analyses, only results from the first analyses will be presented. Specifically, analyses excluding the 72 referred subjects did not substantially decrease any of the reported outcomes.

Results

Subjects assigned to the hearing aid group and the waiting list group were similar with respect to all baseline demographic, clinical, and hearing loss characteristics (Table 1). All patients had either sensorineural defects (97%) or combined sensorineural and conductive defects (3%). The degree of hearing loss (classified by the average loss in the better ear at three frequencies rather than at a single screening frequency) was mild (average, 0 to 40 dB loss) in 70% of subjects, moderate (average, 41 to 55 dB loss) in 27%, and moderately severe (average, 56 to 70 dB loss) in 3% (64).

Most of the hearing aids that were dispensed to the hearing aid group were in-the-ear aids (98%). Aids were usually (97%) fitted monaurally because of financial constraints. In general, the ear with the worse pure-tone thresholds was fitted. The average biologic change in hearing (HFPTA) for the ear that was fitted with the hearing aid was a 28% improvement (95% CI, 26% to 30%; $P < 0.0001$).

Drop-outs and Crossovers

Six subjects (3%) were unable to complete follow-up visits: three in the waiting list group and three in the hearing aid group. Five of the drop-outs were due to deaths, and one was due to a patient moving from the study site area. No persons assigned to the waiting list group received a hearing aid from any other source during the trial period.

Compliance and Cointerventions

At 6 weeks, 15% of persons in the hearing aid group reported wearing their aids less than 4 hours daily, 30% reported 4 to 8 hours of daily use, and 55% reported greater than 8 hours of daily use. There was no statistically detectable change in reported hours of use from baseline to 4 months. The number of batteries dispensed was consistent with the self-reported hours of use. Eighty-eight percent of the hearing aid group had families who also completed hearing aid use questionnaires; these reports corroborated the self-reported hours of use ($r = 0.6$, $P < 0.0001$). Of note, number of hours of hearing aid use was not correlated with any outcome except change in HHIE. Persons who reported greater hours of use had greater improvements on HHIE scores ($r = 0.21$, $P = 0.05$).

During the 4-month trial period, there were no statistically significant changes either between or within groups in the number and type of diagnosed comorbid conditions (for example, hypertension, diabetes, congestive heart failure) or in the number and type of medications dispensed. Three subjects in the waiting list group and four in the hearing aid group had changes made in major diagnoses or sedative and antidepressant medications. (Excluding these persons from analyses did not change results.) There were no statistically detectable differences between groups in the number of outpatient clinic visits or hospital admissions during the trial period. In particular, there were no statistically significant differences between groups in the number of psychiatry or eye clinic visits.

Quality-of-Life Outcomes

There were no statistically significant differences between groups at baseline on any of the quality-of-life measures except for the SPMSQ (Table 2). The hearing

Table 2. Quality-of-Life Scores*

Test	Baseline		4-Month Follow-up	
	Hearing Aid Group	Waiting List Group	Hearing Aid Group	Waiting List Group
HHIE	48.7 (27.3)	51.2 (29.1)	14.7 (17.7)	51.2 (28.0)
QDS	58.7 (24.5)	61.0 (25.4)	35.7 (25.2)	62.2 (24.5)
SPMSQ	0.47 (0.75)	0.18 (0.46)	0.29 (0.66)	0.28 (0.66)
GDS	3.1 (2.81)	3.5 (3.36)	2.6 (2.79)	3.8 (3.57)
SELF	92.7 (16.3)	95.6 (18.0)	92.0 (18.2)	96.8 (18.8)

* Values are expressed as means (SD).

† HHIE = Hearing Handicap Inventory in the Elderly; QDS = Quantified Denver Scale; SPMSQ = Short Portable Mental Status Questionnaire; GDS = Geriatric Depression Scale; and SELF = Self Evaluation of Life Function scale.

Table 3. Average Differences between Groups in Quality-of-Life Change Scores*

Scale	Change†	95% CI	P Value
HHIE	34.0	(27.3, 40.8)	< 0.0001
QDS	24.2	(17.2, 31.2)	< 0.0001
SPMSQ	0.28	(0.08, 0.48)	0.008
GDS	0.80	(0.09, 1.51)	0.03
SELF	1.9	(-1.6, 5.4)	0.27

* HHIE = Hearing Handicap Inventory in the Elderly; QDS = Quantified Denver Scale; SPMSQ = Short Portable Mental Status Questionnaire; GDS = Geriatric Depression Scale; and SELF = Self Evaluation of Life Function scale.

† A positive change indicates an advantage for the hearing aid group.

aid group had a slightly worse SPMSQ score ($P = 0.01$). Sixty-three percent of subjects reported severe social and emotional handicap due to hearing impairment (HHIE score > 42), and 20% reported mild to moderate handicap (HHIE score, 16 to 42). Moderate communication difficulties were reported by 85% of subjects (QDS score > 30). Depression was identified (GDS score > 5) in 23% of subjects, and only 1% were significantly cognitively impaired (SPMSQ > 2).

Treatment effects of hearing aids from baseline to the 4-month follow-up are given in Table 3. Change score improvements in social and emotional function, as assessed by the HHIE (34.0; CI, 27.3 to 40.8; $P < 0.0001$), and communication function, as assessed by the QDS (24.2; CI, 17.2 to 31.2; $P < 0.0001$), were marked in the hearing aid group compared with the waiting list group. Percent improvements in mental status scores (0.28; CI, 0.08 to 0.48; $P = 0.008$) and depression scores (0.80; CI, 0.09 to 1.51; $P = 0.03$) were statistically significant. The point estimate (1.9) for change in global function (assessed by the SELF) was positive, but not statistically significant. Subscale changes within the SELF also were not statistically significant, although borderline statistically significant improvements were found on the depression subscale (1.9; CI, -0.1 to 4.0; $P = 0.07$).

Of note, the HHIE and QDS treatment effects between groups did not change after adjusting for initial SPMSQ scores. Improvements in depression (GDS), however, became borderline statistically significant ($P = 0.06$) after adjustment for initial SPMSQ scores. Improvements in cognition (SPMSQ) were not affected by improvements in depression; SPMSQ changes remained statistically significant even after adjustment for any changes in GDS scores. None of the quality-of-life changes was affected by age. Lastly, no quality-of-life changes within the waiting list group were statistically significant (all P values > 0.10), whereas all quality-of-life changes (except for the change in SELF score) within the hearing aid group represented statistically significant improvements ($P < 0.05$).

The patterns of change from baseline to 6 weeks to 4 months seen with the HHIE and the QDS assessments are shown in Figures 2 and 3, respectively. Social and emotional dysfunction, as assessed by the HHIE, and communication dysfunction, as assessed by the QDS, remained stable for the waiting list group at the 6-week and 4-month follow-up evaluations. In contrast, subjects

given hearing aids had improvements in these areas of function at 6 weeks which were sustained at 4 months. Initial degree of hearing loss (HFPTA) was not correlated with HHIE or QDS improvements ($r = 0.05$, $P = 0.61$).

Most subjects (89%) were living with a spouse or another family member. Ninety-four percent of these families ($n = 162$) completed family reports, allowing us to measure agreement in subject reports of overall improvement in social and communication function with their families' subjective assessments in these areas. The families' assessments and their degree of agreement beyond chance with subjects' assessments are given in Table 4. Marked improvements in overall social (62%; CI, 47% to 77%) and communication (64%; CI, 49% to 79%) function were reported by the subjects in the hearing aid group compared with the waiting list group. Likewise, marked improvements in overall social (55%; CI, 40% to 70%) and communication (58%; CI, 42% to 74%) function were reported by families of subjects who received hearing aids. Almost all patients who received hearing aids and their families were satisfied with the aid. Subject and family responses were positively correlated in all instances.

Discussion

Our randomized controlled trial established that marked social, emotional, and communication difficulties are caused by hearing loss. Severe handicaps in these areas are found even when persons have only mild to moderate audibly detectable hearing loss. Hearing aids are very successful treatments for reversing the social, emotional, and communication dysfunctions caused by hearing impairment. In addition, hearing aids may lead to improvements in cognition and depression.

These results confirm previous cross-sectional reports (14, 19-22, 29, 31) which suggested that acquired hearing loss is associated with social and emotional isolation. They also confirm several "before and after" stud-

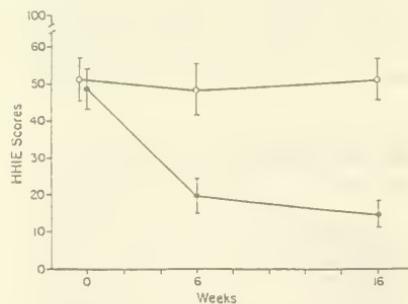


Figure 2. Hearing Handicap Inventory in the Elderly (HHIE) results for both groups at baseline, 6 weeks, and 4 months. The waiting list group results are represented by open circles. The hearing aid group results are represented by closed circles. Differences are significant at the $P < 0.0001$ level.

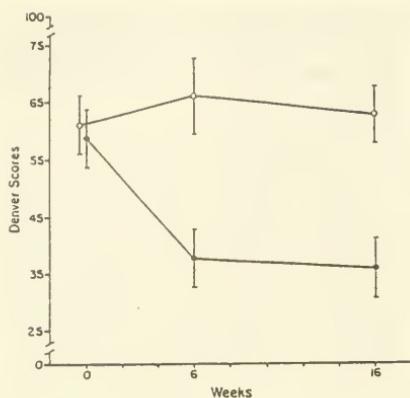


Figure 3. Quantified Denver Scale of Communication Function (Denver Scores) results for both groups at baseline, 6 weeks, and 4 months. The waiting list group results are represented by open circles. The hearing aid group results are represented by closed circles. Differences are significant at the $P < 0.0001$ level.

ies (13, 48, 65-71) that showed improved psychosocial function in hearing impaired persons after hearing aid administration. The findings of improved cognition and affect (depression) with hearing aids are particularly interesting. Several investigators have previously reported an association between cognition and hearing loss (10-12, 24-26); others have been unable to document such a relation (15, 16, 23). Investigators have also reported an association between depression and hearing loss (16-18), which has not always been confirmed (10, 13, 31, 34). As none of the past investigations was a randomized trial, cause-effect relations could not be determined.

Our findings suggest that hearing impairment is related to both cognition and depression. The relation with cognition remains even after adjusting for depression. Hearing aid treatment effects in these areas, however, were relatively small. Other studies are needed to confirm the clinical significance of these cause-effect

relations. To establish the relations better, future studies should be conducted in patient populations with a high prevalence of depression, a more severe spectrum of cognitive impairment (including patients with dementias), or both. Interactions between depression and cognition should continue to be evaluated. Assessments of cognition and affect that are more definitive than the SPMSQ and the GDS should be used.

Effects of hearing aids were more easily detected by the disease-specific instruments (HHIE, QDS) than the generic instruments (SPMSQ, GDS, SELF). The disease-specific measures were expressly developed to test for adverse psychosocial effects due to hearing loss. They were sensitive and specific instruments for assessing dysfunction due to hearing loss and responsive instruments for detecting changes in quality of life seen with hearing aids. Using these measures, beneficial treatment effects were seen as early as 6 weeks after hearing aid administration. These findings confirm previous studies which suggested that the 6 weeks after hearing aid administration represent an adequate follow-up period for assessment of treatment effects (67, 70).

In our trial, the cost of identifying hearing impaired persons, providing formal audiology testing with subsequent hearing aid fitting and orientation sessions, and one follow-up evaluation was approximately \$1000 per hearing aid dispensed. If Hearing Quality Adjusted Life Years (HQALYs) for persons receiving hearing aids are projected based on percent improvements, as assessed by the HHIE (72), cost-effectiveness estimates of only \$200 per HQALY gained are found.

To interpret the results of our randomized trial appropriately, several issues should be considered. The study population consisted almost exclusively of male veterans. Results may not be readily generalizable to women or to persons who vary markedly in socioeconomic, cultural, and clinical characteristics from those who participated in the study.

Some areas of quality of life improved more than others with hearing aid use. These differential effects are probably due to hearing impairment affecting certain dimensions of function (for example, social and communication) more than others (for example, cognition and affect). In addition, differing specificity and responsiveness characteristics of the instruments that were used to assess quality of life could explain some of the

Table 4. Subject and Family Assessments of Overall Improvements in Social and Communication Function and of Hearing Aid Satisfaction*

Improvements	Subject Reports (n = 162)	Family Reports (n = 162)	Family and Subject Agreement†
Social function, %	62 (47, 77)	55 (40, 70)	0.46 (0.30, 0.62)
Communication function, %	64 (49, 79)	58 (42, 74)	0.58 (0.42, 0.74)
Aid satisfaction score‡	18.7 ± 6.2	18.2 ± 6.6	0.27 (0.03, 0.56)
Very satisfied, %	46	54	
Satisfied, %	42	38	

* Social and communication function improvements are for the hearing aid group compared with the waiting list group (positive percentages represent the advantages of the hearing aid group over the waiting list group); satisfaction reports are from only the hearing aid group ($n = 84$). The numbers in parentheses are 95% confidence intervals (CIs).

† Family and subject agreement for social and communication assessments were estimated with weighted Kappa statistics and aid satisfaction agreement, with an intraclass correlation coefficient.

‡ Values are means ± SD.

variation in effects. In particular, the instruments used to assess cognition (SPMSQ) and affect (GDS) are commonly used simple screening tools that were not originally developed to detect changes in function. Use of more specific and detailed instruments to assess cognition and affect could have resulted in greater changes being seen in these areas.

As the primary outcome measures were subjective self-assessments and the study was not blinded (sham in-the-ear hearing aids that did not alter hearing in any way were not possible), positive quality-of-life changes could have been potentiated by placebo and Hawthorne effects. Hopefully, such effects were minimized because both hearing aid subjects and waiting list subjects received equivalent care and follow-up except for the one extra orientation visit given to hearing aid subjects and because all outcome measures were administered in a similar standardized fashion. In addition, the observed biologic improvements in hearing, the very large magnitude of quality-of-life improvements that were sustained throughout the 4-month trial period, and the relative specificity of the large quality-of-life changes in the areas of communication and social function are unlikely to be due solely to placebo and Hawthorne effects.

Despite limitations, our randomized controlled trial has established that hearing aids improve the quality of life of elderly persons with hearing loss. Improvements in several areas (including social, emotional, and communication function; affect or depression; and cognition) were seen. The benefits of hearing aids were experienced as early as 6 weeks after administration and were better assessed with disease-specific rather than generic quality-of-life instruments.

The implications of these results are myriad. First, health care providers should no longer ignore screening for hearing loss on the basis that hearing aids are not effective; clearly, they have been proved beneficial. Second, hearing loss may contribute to impaired cognition and depression. Third, potential functional status benefits of hearing aids are best detected with disease-specific hearing handicap scales such as the HHIE. Finally, rigorous cost-effectiveness analyses are now warranted to confirm that hearing aids represent a relatively inexpensive therapy for the amount of benefit gained. We hope that these results will guide government and third-party payers in reconsidering current policies that do not allow reimbursement for hearing aids.

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September 14, 1993

U.S. Senator David Pryor
Senate Russell Office Building
P.O. Box 20510
Washington, DC 20510

Dear Senator Pryor:

Per request of Mr. Greg Smith of your staff I am sending you background materials on Wisconsin's Hearing and Speech Examining Board. This joint regulatory board, housed within the Wisconsin Department of Regulation and Licensing, has eight members: three traditional dispensers, one otolaryngologist, one audiologist, two public (consumer) members and one speech language pathologist.

Some have suggested Wisconsin's "joint board" model is one that may be of interest to your committee. We are happy to assist you and your committee in any way we can and by this letter recognize and extend our appreciation to Senators Kohl and Feingold for their interest in hearing health care.

The Wisconsin Alliance of Hearing Professionals consists of audiologists who dispense hearing instruments and traditional dispensers. Collectively our members share a common interest in quality care for the hearing impaired.

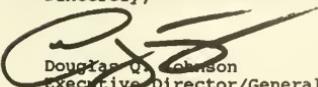
We are concerned about access to hearing health care and the cost of that care. Please consider that the hearing impaired are also often mobility impaired and any regulation of the dispensing profession must address access and cost.

Regulation of the dispensing profession should recognize the role of the states. While there may be abuses justifying increased federal involvement in some states, that is not the Wisconsin story (you may want to contact Governor Tommy Thompson or Department of Regulation and Licensing Secretary Marlene Cummings (608) 266-8609).

Thank you for the opportunity to include this letter and the attached materials in your committee's record. We ask that your committee be wary of "reform" that disenfranchises thousands of hearing impaired citizens from quality hearing health care such as that available in Wisconsin.

If we can be of further assistance, please advise.

Sincerely,


Douglas O. Johnson
Executive Director/General Counsel

cc: Senator Feingold c/o Mr. Sumner Schlichter
Senator Kohl c/o Mr. Mark Curtis
Governor Tommy Thompson
Department of Regulation & Licensing
Secretary Marlene Cummings
Alliance Board

459.01 HEARING AND SPEECH EXAMINING BOARD

89-90 Wis. Stats. 3810

CHAPTER 459

HEARING AND SPEECH EXAMINING BOARD

SUBCHAPTER I LICENSURE OF HEARING INSTRUMENT SPECIALISTS		SUBCHAPTER II LICENSURE OF SPEECH-LANGUAGE PATHOLOGISTS AND AUDIOLOGISTS	
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459.10 Temporary permits.	459.40 Definitions.		
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SUBCHAPTER I

LICENSURE OF HEARING INSTRUMENT SPECIALISTS

459.01 Definitions. As used in this subchapter, unless the context clearly indicates a different meaning:

(1) "Examining board" means the hearing and speech examining board.

(2) "Hearing aid" means any wearable instrument or device designed for or offered for the purpose of aiding or compensating for impaired human hearing and any parts, attachments or accessories of such an instrument or device, except batteries and cords.

(3) "Hearing instrument specialist" means any person who is or is required to be licensed under s. 459.05 to engage in the practice of dealing in or fitting hearing aids.

(4) "License" means a license issued by the department under s. 459.03, to hearing aid dealers or firms.

(5) "Practice of fitting and dealing in hearing aids" means the measurement of human hearing by means of an audiometer or by any other means accepted by the examining board solely for the purpose of making selections, adaptations or sales of hearing aids intended to compensate for impaired hearing. This term also includes making impressions for ear molds.

(6) "Sell" or "sale" means a transfer for a consideration of title or of the right to use.

(7) "Trainee permit" means a temporary permit issued while the applicant is in training to become a licensed hearing instrument specialist.

History: 1953 s. 109; 1969 s. 316.

459.02 License required to sell and fit hearing aids. (1) No person may engage in the practice of selling or fitting hearing aids or display a sign or in any other way advertise or represent himself or herself as a person who practices the fitting or sale of hearing aids unless he or she holds a valid license issued under this subchapter. The license required by s. 459.05 shall be conspicuously posted in his or her office or place of business as registered with the department at all times. Duplicate licenses shall be issued by the department to valid license holders operating more than one office without additional payment.

(2) Nothing in this subchapter shall prohibit any corporation or mercantile establishment which maintains an established business address from engaging in the business of selling or offering for sale hearing aids at retail without a license, provided that for the purpose of selling and fitting hearing aids it employs persons licensed under this subchapter. Such corporation or mercantile establishment shall annually file with the examining board a list of all persons employed for the purpose of selling and fitting hearing aids.

History: 1979 c. 162; 1989 s. 316.

459.03 Receipt required to be furnished to a person supplied with hearing aid. (1) Whoever practices fitting or sale of hearing aids shall deliver to each person supplied with a hearing aid a receipt. The receipt shall contain the licensee's signature and show his business address and the number of his certificate, together with specifications as to the make and model of the hearing aid furnished and full terms of sale clearly stated. If a hearing aid which is not new is sold, the receipt and the container thereof must be clearly marked as "used" or "reconditioned" whichever is applicable.

(2) The following shall be set out in not less than 6-point type:

(a) The terms of the guarantee, if there is any given; and

(b) A statement that the purchaser has been advised at the outset of his relationship with the hearing instrument specialist that any examination or representation made by a hearing instrument specialist in connection with the fitting and selling of this hearing aid is not an examination, diagnosis or prescription by a person licensed to practice medicine in this state and therefore must not be regarded as medical opinion or advice.

History: 1969 s. 316.

459.035 Medical exam before being fitted. A hearing aid shall not be fitted for or sold to a child 16 years of age or younger unless within 90 days prior to the fitting the person to be fitted has been examined by a physician to determine whether or not he or she has any physical deficiencies that would prohibit the effective use of a hearing aid.

History: 1979 c. 162 s. 38 (6).

459.04 Seller's guarantee. The seller of a hearing aid shall give to the purchaser a personal guarantee that is at least

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identical in its terms to the guarantee of the manufacturer of the hearing aid.

488.05 Issuance of license. The department shall register each applicant who passes an examination as provided in s. 499.06 and shall issue to the applicant a certificate of license signed by the secretary of regulation and licensing. The certificate of license shall be effective until January 30th of the year following the year in which it is issued.

(1) Whenever the examining board determines that another state or jurisdiction has requirements equivalent to or higher than those in effect in the state for the practice of fitting and selling hearing aids, and that such state or jurisdiction has a program equivalent to or stricter than the program for determining whether applicants in this state are qualified to fit and sell hearing aids, the department may issue a license by reciprocity to applicants who hold valid certificates or licenses to deal in or fit hearing aids in such other state or jurisdiction and is otherwise qualified for licensure. No such applicant for a license by reciprocity under this subsection shall be required to submit to or undergo a qualifying examination, other than the payment of the fee under s. 440.05 (2) provided the applicant personally appears at the next meeting of the examining board after filing the application to answer any questions the examining board has. The holder of a license by reciprocity shall be registered in the same manner as other holders of a license. Grounds for renewal and procedures for reprimand or for the limitation, suspension and revocation of a license by reciprocity shall be the same as for reprimand, renewal, limitation, suspension and revocation of a license.

(2) Any person may be issued a license without examination if he or she held a valid license issued by this examining board which expired not more than one year prior to the date of application.

History: 1973 c. 224; 1977 c. 29, 41R; 1979 c. 163 s. 36 (4).

488.06 License by examination. (1) Applicants may obtain a license by successfully passing a qualifying examination, provided the applicant is 18 years of age or older, does not have an arrest or conviction record, subject to ss. 111.321, 111.322 and 111.333, and has an education equivalent to a 4-year course in an accredited high school.

(2) The examination shall include but not be limited to:

(a) Tests of knowledge in the following areas as they pertain to the fitting of hearing aids:

1. Basic physics of sound.

2. The anatomy and physiology of the ear.

3. The function of hearing aids.

(b) Practical tests of proficiency in the following techniques as they pertain to the fitting of hearing aids:

1. Pure tone audiometry, including air conduction testing and bone conduction testing.

2. Live voice or recorded voice speech audiometry including speech reception threshold testing and most comfortable loudness measurements and measurements of tolerance thresholds.

3. Masking when indicated.

4. Recording and evaluation of audiograms and speech audiometry to determine proper selection and adaption of a hearing aid.

5. Taking ear mold impressions.

(3) The applicant for license by examination shall appear at a time and place as the examining board designates, to be examined by means of written and practical tests in order to demonstrate that he or she is qualified to practice the fitting of hearing aids. Such examinations shall be conducted at

least twice a year and at such other times and places designated by the examining board.

(4) Applications for examinations shall be submitted to the examining board at least 30 days before the date set for the examination and shall be accompanied by the examination fee specified under s. 440.05 (1).

History: 1973 c. 224; 1977 c. 29; 1979 c. 163 s. 38 (4); 1981 c. 391 s. 21; 1983 c. 221.

488.07 Temporary trainee permit. (1) An applicant who fulfills the requirements regarding age, character and high school education as set forth in s. 459.06, may obtain a trainee permit upon application to the examining board. The name of the licensee who is supervising the trainee shall appear on the face of the permit.

(2) Upon receiving an application under this section, accompanied by the fee under s. 440.05 (6), the examining board may grant a trainee permit which may entitle the applicant to practice fitting of hearing aids for a period of one year. A person holding a valid hearing aid dealers or fitters license shall be responsible for the direct supervision and training of the applicant and shall be liable for all negligent acts and omissions of the trainee in the fitting of hearing aids.

(3) A trainee permit may be renewed or regranted once if the trainee shows that he or she had sufficient cause for being unable to complete the requirements for permanent licensure.

(4) The examining board shall encourage the establishment of educational courses for the training of all persons wishing to become licensed hearing aid dealers and fitters.

History: 1977 c. 29; 1979 c. 163 s. 38 (4).

488.08 Notice to department of place of practice; notice to holders of license; how given. (1) A person who holds a license shall notify the department in writing of the regular address of the places where he or she engages or intends to engage in the practice of fitting or selling hearing aids. The licensee shall inform the board of any changes in these addresses within 30 days of the change.

(2) The department shall keep a record of the places of practice of persons who hold licenses.

(3) Any notice required to be given by the department to a person who holds a license shall be mailed to the person by registered or certified mail at the address of the last place of practice of which he or she has notified the department.

History: 1979 c. 163 ss. 37, 38 (4); 1983 c. 221.

488.09 Calibration of audiometric equipment. Audiometric equipment used in the evaluation of hearing sensitivity for the fitting and sale of hearing aids shall be calibrated not less than once every 6 months. Certification of these calibrations shall be sent to the examining board with the renewal fee required in s. 459.09.

488.09 Renewal of license; fees; effect of failure to renew. Each person who practices dealing in or fitting hearing aids shall, on or before January 30 of even-numbered years following licensure, pay to the department the renewal fee specified in s. 440.05 (3) and keep the certificate conspicuously posted in the person's office or place of business at all times. Where more than one office is operated by the licensee, duplicate certificates shall be issued by the department for posting in each location.

History: 1977 c. 29.

488.10 Disciplinary grounds. (1) Subject to subch. II of ch. 111 and the rules adopted under s. 440.01 (1), the examining board may reprimand the licensee or permit holder or revoke, suspend, limit or deny the trainee permit or license, or any

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combination thereof, of any person who has done any of the following:

(a) Made any false statement or given any false information in connection with an application for a license or trainee permit or for renewal or reinstatement of a license or trainee permit.

(b) Been issued a license or trainee permit through error.

(c) Been adjudicated mentally incompetent by a court.

(d) Been found guilty of an offense the circumstances of which substantially relate to the practice of fitting and dealing in hearing aids.

(e) Violated this subchapter or ch. 440 or any federal or state statute or rule which relates to the practice of fitting and dealing in hearing aids.

(f) Practiced as a hearing instrument specialist while the person's ability to practice was impaired by alcohol or other drugs or physical or mental disability or disease.

(g) Engaged in false, misleading or deceptive advertising.

(h) Made a substantial misrepresentation in the course of practice which was relied upon by a client or patient.

(i) Failed to conduct a direct observation of the purchaser's ear canal.

(j) Engaged in conduct which evidenced a lack of knowledge or ability to apply principles or skills of the practice of fitting and dealing in hearing aids.

(k) Engaged in unprofessional conduct. In this subsection, "unprofessional conduct" means the violation of any standard of professional behavior which through experience, state statute or administrative rule has become established in the practice of fitting and dealing in hearing aids.

(L) Obtained or attempted to obtain compensation by fraud or deceit.

(m) Violated any order of the examining board.

(n) Knowingly employed directly or indirectly, to perform any work regulated under this subchapter, any person not licensed or not holding a trainee permit under this subchapter, or whose license or trainee permit has been suspended or revoked.

(o) Permitted another person to use his or her license or trainee permit.

(p) Sold a hearing aid to a person who was not given tests using appropriate procedures and instrumentation or without proper measurement of the functional intensity and range of the person's hearing.

(q) (a) An individual whose license or trainee permit is limited by the examining board may continue to practice under the license or permit if the individual does all of the following:

1. Refrains from engaging in unprofessional conduct.

2. Appears before the examining board or its officers or agents upon each request of the examining board.

3. Fully discloses to the examining board or its officers or agents the nature of the individual's practice and conduct.

4. Fully complies with the limits placed on his or her practice and conduct by the examining board.

5. Obtains any additional training, education or supervision required by the examining board.

6. Cooperates with all reasonable requests of the examining board.

(b) The examining board may, as a condition of removing a limitation on a license or trainee permit issued under this subchapter or of reinstating a license or trainee permit that has been suspended or revoked under this subchapter, require the licensee or permit holder to obtain minimum results specified by the examining board on one or more physical, mental or professional competency examinations if the examining board determines that obtaining the minimum results is

related to correcting one or more of the bases upon which the limitation, suspension or revocation was imposed.

(c) The examining board may, as a condition of reinstating a license that has been suspended under this subchapter, require the license holder to pass the examination required for initial licensure under s. 459.06.

History: 1983 a. 229; 1989 a. 316.

459.105 Injunction. If it appears upon complaint to the examining board by any person or is known to the examining board that any person is practicing as a hearing instrument specialist without a license or trainee permit, the examining board, the attorney general or the district attorney of the proper county may investigate and may, in addition to any other remedies, bring an action in the name and on behalf of this state against the person to enjoin the person from practice.

History: 1983 a. 229; 1989 a. 316.

459.11 Testing equipment. The examining board may, in addition to any other power granted, purchase and maintain or rent audiometric equipment and facilities necessary to carry out the examination of applicants for licenses.

459.12 Rules. (1) The examining board may make rules not inconsistent with the laws of this state which are necessary to carry out the intent of this subchapter.

(2) The examining board shall by rule establish standards for the calibrations and certifications required by s. 459.05.

(3) The examining board shall by rule prescribe the number of trainees a licensee may supervise under s. 459.07.

History: 1989 a. 316.

459.13 Penalty. Any person violating this subchapter or any rule promulgated under this subchapter shall forfeit not more than \$500.

History: 1989 a. 316.

459.14 Exemptions. (1) This subchapter does not apply to a physician licensed by the medical examining board.

(2) This subchapter does not apply to a person engaged in the practice of measuring human hearing for selecting hearing aids or any other purpose if the person or the organization employing such person does not sell hearing aids or hearing accessories.

History: 1989 a. 316.

SUBCHAPTER II

LICENSURE OF SPEECH-LANGUAGE PATHOLOGISTS AND AUDIOLOGISTS

459.20 Definitions. In this subchapter:

(1) "Audiologist" means an individual engaged in the practice of audiology.

(2) "Audiology" means applying principles, methods or procedures of prevention, identification, evaluation, consultation, intervention, instruction or research related to hearing, vestibular function, or any abnormal condition related to timor, auditory sensitivity, acuity, function or processing speech, language or other aberrant behavior resulting from hearing loss.

(3) "Examining board" means the hearing and speech examining board.

(3m) "Licensee" means an individual licensed under this subchapter.

(4) "Speech-language pathologist" means an individual engaged in the practice of speech-language pathology.

(5) "Speech-language pathology" means applying principles, methods or procedures of prevention, identification, evaluation, consultation, intervention, instruction or research related to speech, language, cognition or swallowing or any abnormal condition involving speech, articulation, fluency, voice, verbal or written language, auditory comprehension, cognition or communication or oral, pharyngeal or laryngeal sensorimotor competencies.

History: 1989 s. 314.

459.22 Applicability. (1) This subchapter applies after June 30, 1993.

(2) This subchapter does not do any of the following:

(a) Authorize an individual licensed under this subchapter to engage in any practice for which a license is required under ch. 468.

(b) Authorize an individual licensed under this subchapter to dispense or sell hearing aids without obtaining a hearing instrument specialist license under subch. I.

(c) Require a hearing instrument specialist licensed under subch. I to be licensed as an audiologist under this subchapter to engage in the testing of hearing or in other practices or procedures solely for the purpose of fitting or selling hearing aids.

(d) Require an individual who engages in the practice of speech-language pathology or audiology as part of a supervised course of study, including an internship or clinical practicum, leading to a degree in speech-language pathology or audiology at a college or university to be licensed under this subchapter if the individual is designated by a title which clearly indicates status as a student or trainee.

(e) Require an employee of a speech-language pathologist or audiologist to be licensed under this subchapter to assist in the practice of speech-language pathology or audiology under the direct supervision of the speech-language pathologist or audiologist.

(f) Require an individual to be licensed under this subchapter to engage in the practice of speech-language pathology or audiology in a position for which the department of public instruction requires licensure as a speech and language pathologist.

History: 1989 s. 314.

459.23 Duties of council on speech-language pathology and audiology. The council on speech-language pathology and audiology shall advise the examining board on matters pertaining to the establishment of codes of ethics, the imposition of discipline, the granting of licenses and the formulation of proposed rules relating to licensure and, upon request of the examining board, on any other matter relating to licensure.

History: 1989 s. 316.

459.24 Licensure. (1) LICENSE REQUIRED. Except as provided under s. 459.22, no person may do any of the following:

(a) Engage in the practice of speech-language pathology or use the title "speech-language pathologist" or any similar title unless the person holds a current speech-language pathologist license granted by the examining board.

(b) Engage in the practice of audiology or use the title "audiologist", "clinical audiologist" or any similar title unless the person holds a current audiologist license granted by the examining board.

(1m) PROHIBITED TITLE. No person may use the title "certified hearing aid audiologist" or "licensed hearing aid audiologist".

(2) SPEECH-LANGUAGE PATHOLOGIST LICENSE. The examining board shall grant a speech-language pathologist license to an individual who does all of the following:

(a) Submit an application for the license to the department on a form provided by the department.

(b) Pays the fee specified in s. 440.05 (1).

(c) Subject to ss. 111.321, 111.322 and 111.335, submits evidence satisfactory to the examining board that he or she does not have a conviction record.

(d) Submits evidence satisfactory to the examining board that he or she has completed a supervised clinical practicum and received a master's degree in speech-language pathology from a college or university approved by the examining board, or has completed education or training that the examining board determines is substantially equivalent to the completion of those requirements.

(e) Submits evidence satisfactory to the examining board that he or she has passed the examination required for certification as a speech-language pathologist by the American speech-language-hearing association or passes an examination under s. 459.26 to determine fitness as a speech-language pathologist.

(f) Submits evidence satisfactory to the examining board that he or she has completed a postgraduate clinical fellowship in speech-language pathology approved by the examining board.

(3) AUDIOLOGIST LICENSE. The examining board shall grant an audiologist license to an individual who does all of the following:

(a) Submits an application for the license to the department on a form provided by the department.

(b) Pays the fee specified in s. 440.05 (1).

(c) Subject to ss. 111.321, 111.322 and 111.335, submits evidence satisfactory to the examining board that he or she does not have a conviction record.

(d) Submits evidence satisfactory to the examining board that he or she has completed a supervised clinical practicum and received a master's degree in audiology from a college or university approved by the examining board, or has completed education or training that the examining board determines is substantially equivalent to the completion of those requirements.

(e) Submits evidence satisfactory to the examining board that he or she has passed the examination required for certification as an audiologist by the American speech-language-hearing association or passes an examination under s. 459.26 to determine fitness as an audiologist, or has completed education or training that the examining board determines is substantially equivalent to passing one of those examinations in determining fitness as an audiologist.

(f) Submits evidence satisfactory to the examining board that he or she has completed a postgraduate clinical fellowship in audiology approved by the examining board or has completed education or training that the examining board determines is substantially equivalent to the completion of such a fellowship.

(4) POSTING OF LICENSE CERTIFICATE. The department shall issue a certificate to each licensee, certifying that the holder is licensed to practice speech-language pathology or audiology. The licensee shall post the certificate in a conspicuous place in the licensee's place of business.

(5) EXPIRATION AND RENEWAL. Licenses issued under this subchapter expire on February 1 of each odd-numbered year. Renewal applications shall be submitted to the department on a form provided by the department and shall include the renewal fee specified in the rules promulgated under s. 459.31.

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(6) **TEMPORARY LICENSE.** (a) Upon application, the examining board may grant a temporary license to practice speech-language pathology during the completion of the postgraduate fellowship required under sub. (2) (f) if the applicant practices under the supervision of a speech-language pathologist licensed under sub. (2), satisfies the requirements under sub. (2) (a) to (d) and has submitted an application to take the next available examination for licensure as a speech-language pathologist under s. 459.26.

(b) Upon application, the examining board may grant a temporary license to practice audiology during the completion of the postgraduate fellowship required under sub. (3) (f) if the applicant practices under the supervision of an audiologist licensed under sub. (3), satisfies the requirements under sub. (3) (a) to (d) and has submitted an application to take the next available examination for licensure as an audiologist under s. 459.26.

(c) A temporary license granted under this subsection is valid for a period designated by the examining board, not to exceed 9 months, and may be renewed once by the examining board. An applicant for a temporary license shall pay the temporary license fee specified in the rules promulgated under s. 459.33.

History: 1989 s. 316.

459.25 Examination. (1) The examining board shall conduct examinations for speech-language pathologist and audiologist licensure at least semiannually and at times and places determined by the examining board. The examining board shall provide public notice of each examination at least 60 days before the date of the examination.

(2) Examinations shall consist of the examinations required for certification as a speech-language pathologist or as an audiologist by the American speech-language-hearing association or may consist of other written tests that require applicants to demonstrate minimum competency in services and subjects substantially related to the practice of speech-language pathology or audiology and that are substantially equivalent to the examinations required for such certification.

(3) An individual is not eligible for examination unless he or she has satisfied the requirements for licensure under s. 459.24 (2) (a) to (d) and, at least 30 days before the date of examination, submits an application for examination to the department on a form provided by the department and pays the specified fee in s. 440.05 (1).

History: 1989 s. 316.

459.26 Licensees of other jurisdictions. (1) Upon application and payment of the reciprocal license fee specified in the rules promulgated under s. 459.33, the examining board shall grant a license to practice speech-language pathology or audiology under s. 459.24 (2) or (3) to an applicant who holds a current speech-language pathologist or audiologist license in another state or territory of the United States if the examining board determines that the requirements for licensure in the other state or territory are substantially equivalent to the requirements under s. 459.24 (2) or (3).

(2) The examining board may enter into reciprocal agreements with officials of other states or territories of the United States for licensing speech-language pathologists and audiologists and grant licenses to applicants who are licensed in those states or territories according to the terms of the reciprocal agreements.

History: 1989 s. 316.

459.28 Restoration of license. Any individual licensed as a speech-language pathologist or audiologist who fails to re-

new the license before its expiration date may renew the license as follows:

(1) If the application for renewal is submitted to the department not more than 2 years after the expiration of the applicant's license, by payment of the renewal fee specified in the rules promulgated under s. 459.33 and the fee specified in s. 440.05 (4) or (5).

(2) If the application for renewal is submitted to the department more than 2 years after the expiration of the applicant's license, by payment of the fee specified in s. 440.05 (1) and successful completion of the appropriate examination under s. 459.26.

History: 1989 s. 316.

459.32 Limited permit. (1) Upon application, the examining board shall grant a permit to practice speech-language pathology in association with a speech-language pathologist licensed under s. 459.24 (2), or to practice audiology in association with an audiologist licensed under s. 459.24 (3), to an individual who is not a resident of this state if the individual submits evidence satisfactory to the examining board of having satisfied the requirements for licensure under s. 459.24 (2) (c) and (d) or (3) (c) and (d). The permit shall be valid for the period designated by the examining board, not to exceed 10 days in any calendar year.

(2) Upon application, the examining board shall grant a permit to practice speech-language pathology or audiology to an individual who is not a resident of this state if the individual holds a current speech-language pathologist or audiologist license in another state or territory of the United States and the examining board determines that the requirements for licensure in the other state or territory are substantially equivalent to the requirements under s. 459.24 (2) or (3). The permit shall be valid for the period designated by the examining board, not to exceed 45 days in any calendar year.

(3) An applicant for a limited permit under sub. (1) or (2) shall pay the limited permit fee specified in the rules promulgated under s. 459.33.

History: 1989 s. 316.

459.33 Fees. The department shall, by rule, establish the amount of the fees required under ss. 459.24 (5) and (6) (e), 459.28 (1), 459.30 (1) and 459.32 (3). The fees shall be based on the approximate cost of the regulation.

History: 1989 s. 316.

459.34 Disciplinary proceedings and actions. (1) Subject to the rules promulgated under s. 440.03 (1), the examining board may make investigations and conduct hearings to determine whether a violation of this subchapter or any rule promulgated under this subchapter has occurred.

(2) Subject to the rules promulgated under s. 440.03 (1), the examining board may reprimand a licensee or permittee or deny, limit, suspend or revoke a license or permit under this subchapter if it finds that the applicant, licensee or permittee has done any of the following:

(a) Made a material misstatement in an application for a license or permit or for renewal of a license.

(b) Engaged in conduct in the practice of speech-language pathology or audiology which evidences a lack of knowledge or ability to apply professional principles or skills.

(c) Subject to ss. 111.321, 111.322 and 111.335, been convicted of an offense the circumstances of which substantially relate to the practice of speech-language pathology or audiology.

(d) Advertised in a manner which is false, deceptive or misleading.

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(e) Advertised, practiced or attempted to practice under another's name.

(f) Subject to ss. 111.321, 111.322 and 111.34, practiced speech-language pathology or audiology while the individual's ability to practice was impaired by alcohol or other drugs.

(g) Violated this subchapter or any rule promulgated under this subchapter.

(h)(1) An individual whose license or limited permit is issued by the examining board may constitute to practice under the license or permit if the individual does all of the following:

1. Refrains from engaging in unprofessional conduct.

2. Appears before the examining board or its officers or agents upon each request of the examining board.

3. Fully discloses to the examining board or its officers or agents the nature of the individual's practice and conduct.

4. Fully complies with the limits placed on his or her practice and conduct by the examining board.

5. Obtains any additional training, education or supervision required by the examining board.

6. Cooperates with all reasonable requests of the examining board.

(b) The examining board may, as a condition of removing a limitation on a license or limited permit issued under this subchapter or of reinstating a license or limited permit that has been suspended or revoked under this subchapter, require the license or permit holder to obtain minimum results specified by the examining board on one or more physical, mental or professional competency examinations if the examining board determines that obtaining the minimum results is related to correcting one or more of the bases upon which the limitation, suspension or revocation was imposed.

(c) The examining board may, as a condition of reinstating a license that has been suspended under this subchapter, require the license holder to pass the examination required for initial licensure under s. 459.26.

(d) In addition to or in lieu of a reprimand or denial, limitation, suspension or revocation of a license or permit under sub. (2), the examining board may assess against an applicant, licensee or permittee a forfeiture of not less than \$100 nor more than \$2,500 for each violation enumerated under sub. (2).

History: 1989 & 216.

SUBCHAPTER III

REGISTRATION OF SPEECH-LANGUAGE PATHOLOGISTS AND AUDIOLOGISTS

458.46 Definitions. In this subchapter:

(1) "Audiologist" means an individual engaged in the practice of audiology.

(2) "Audiology" means applying principles, methods or procedures of prevention, identification, evaluation, consultation, intervention, instruction or research related to hearing, vestibular function, or any abnormal condition related to timpanus, auditory sensitivity, acuity, function or processing, speech, language or other aberrant behavior resulting from hearing loss.

(3) "Examining board" means the hearing and speech examining board.

(3m) "Registrant" means an individual registered under this subchapter.

(4) "Speech-language pathologist" means an individual engaged in the practice of speech-language pathology.

(5) "Speech-language pathology" means applying principles, methods or procedures of prevention, identification, evaluation, consultation, intervention, instruction or research related to speech, language, cognition or swallowing or any abnormal condition involving speech, articulation, fluency, voice, verbal or written language, auditory comprehension, cognition or communication or oral, pharyngeal or laryngeal sensorimotor competencies.

History: 1989 & 216.

458.42 Applicability. (1) This subchapter applies during the period beginning on December 1, 1990, and ending on June 30, 1993.

(2) This subchapter does not do any of the following:

(a) Authorize an individual registered under this subchapter to engage in any practice for which a license is required under ch. 448.

(b) Authorize an individual registered under this subchapter to dispense or sell hearing aids without obtaining a hearing instrument specialist license under subch. L.

(c) Require a hearing instrument specialist licensed under subch. L to be registered as an audiologist under this subchapter to engage in the testing of hearing or in other practices or procedures solely for the purpose of fitting or selling hearing aids.

(d) Require an individual who engages in the practice of speech-language pathology or audiology as part of a supervised course of study, including an internship or clinical practicum, leading to a degree in speech-language pathology or audiology at a college or university to be registered under this subchapter if the individual is designated by a title which clearly indicates status as a student or trainee.

(e) Require an employee of a speech-language pathologist or audiologist to be registered under this subchapter to assist in the practice of speech-language pathology or audiology under the direct supervision of the speech-language pathologist or audiologist.

(f) Require an individual to be registered under this subchapter to engage in the practice of speech-language pathology or audiology in a position for which the department of public instruction requires licensure as a speech and language pathologist.

History: 1989 & 216.

458.44 Duties of council on speech-language pathology and audiology. The council on speech-language pathology and audiology shall advise the examining board on matters pertaining to the establishment of codes of ethics, the imposition of discipline, the granting of certificates of registration and the formulation of proposed rules relating to registrants and, upon request of the examining board, on any other matter relating to registrants.

History: 1989 & 216.

458.46 Registration. (1) REGISTRATION REQUIRED. No person may do any of the following:

(a) Engage in the practice of speech-language pathology or use the title "speech-language pathologist" or any similar title unless the person is registered as a speech-language pathologist under this section.

(b) Engage in the practice of audiology or use the title "audiologist", "clinical audiologist" or any similar title unless the person is registered as an audiologist under this section.

(1m) PROHIBITED TITLES. No person may use the title "certified hearing aid audiologist" or "licensed hearing aid audiologist".

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§9.90 Wis. Stats. 3816

(2) SPEECH-LANGUAGE PATHOLOGIST OR AUDIOLOGIST CERTIFICATE. The examining board shall grant a certificate of registration as a speech-language pathologist or as an audiologist to an individual who does all of the following:

(a) Submit an application for the certificate to the department on a form provided by the department.

(b) Pays a \$50 registration fee.

(c) Subject to ss. 111.321, 111.322 and 111.335, submits evidence satisfactory to the examining board that he or she does not have a conviction record.

(3) POSTING OF CERTIFICATE. The department shall issue a certificate to each registrant, certifying that the holder is registered to practice speech-language pathology or audiology. The registrant shall post the certificate in a conspicuous place in the registrant's place of business.

(4) EXPIRATION OF CERTIFICATE. Certificates issued under this section expire on July 1, 1993, and may not be renewed.

(5) DISCIPLINARY PROCEEDINGS AND ACTIONS. (a) Subject to the rules promulgated under s. 440.03 (1), the examining board may make investigations and conduct hearings to determine whether a violation of this section or any rule promulgated under this section has occurred.

(b) Subject to the rules promulgated under s. 440.03 (1), the examining board may reprimand a registrant or deny, limit, suspend or revoke a certificate under this section if it finds that the applicant or registrant has done any of the following:

1. Made a material misstatement in an application for a certificate.

2. Engaged in conduct in the practice of speech-language pathology or audiology which evidences a lack of knowledge or ability to apply professional principles or skills.

3. Subject to ss. 111.321, 111.322 and 111.335, been convicted of an offense the circumstances of which substantially relate to the practice of speech-language pathology or audiology.

4. Advertised in a manner which is false, deceptive or misleading.

5. Advertized, practiced or attempted to practice under another's name.

6. Subject to ss. 111.321, 111.322 and 111.34, practiced speech-language pathology or audiology while the individual's ability to practice was impaired by alcohol or other drugs.

7. Violated this section or any rule promulgated under this section.

(c) In addition to or in lieu of a reprimand or denial, limitation, suspension or revocation of a certificate under par. (b), the examining board may assess against an applicant or registrant a forfeiture of not less than \$100 nor more than \$2,500 for each violation enumerated under par. (b).

Hawley 1989 s. 216.



Wisconsin Alliance of Hearing Professionals

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August 30, 1993

MEMORANDUM

TO: Alliance Board Members
FROM: Douglas Q. Johnson
Executive Director, General Counsel
RE: National Report on Licensing Boards

Attached please find a copy of the recently released report on state examining boards responsible for hearing instrument dispensing. Wisconsin stands out as a national model (not specifically stated but easily concluded by comparing board/department, structure/operation with recommended standards and other states).

Please feel free to share your comments. By this memo I thank Department of Regulation and Licensing Secretary Marlene Cummings for sending me this report.

cc: Dept. of Regulation and Licensing Secretary Cummings

AUG 27 1993

Hearing Aid
Dispenser State
Licensing Boards
Report of a National Survey

Resource Briefs

By
Peter Powers
and
Eleanor Lewis



The Council on Licensure, Enforcement and Regulation
an affiliate of The Council of State Governments

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Each Resource Brief represents the opinions of the author(s), and is not to be considered an endorsement by CLEAR.

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HEARING AID DISPENSER STATE LICENSING BOARDS: REPORT OF A NATIONAL SURVEY

By
Patricia Powers
School of Social Work
University of Maryland at Baltimore
 and
Eleanor J. Lewis
Washington, D.C.

Introduction and Highlights of Consumer Study

Licensure, enforcement and regulation can protect hearing aid users. In the late 1980s, Vermont's Attorney General argued in favor of the need for licensure of hearing aid dispensers to protect "especially vulnerable" people. In his opinion, regulation was needed to address the following consumer problems:

- ▶ Inappropriate prescription of hearing aids
- ▶ Dealer incompetence
- ▶ Overuse of physician-evaluation waivers
- ▶ Abusive door-to-door sales tactics
- ▶ Deceptive advertising
- ▶ Failure to provide refunds and related problems
- ▶ Excessively high prices
- ▶ Inadequate contract disclosures.¹

Vermont passed a licensure law to protect the hearing impaired. Recent consumer research, however, indicates that licensure alone is insufficient.

A 1991 survey of state hearing aid dispenser licensing boards found that ten states had not taken disciplinary actions against licensees in the preceding three years, and another twelve were only minimally active. Most boards have adequate disciplinary powers but they rarely take disciplinary action against licensees.

Some states still allow regulated personnel to dominate the regulatory boards, constituting 50 percent or more of a board's members in 25 states, and five boards have no public members. Many boards do not maximize their role in consumer protection, with most states receiving fewer than 50 complaints per year. The survey reveals that the easier the procedure for making complaints, the more consumer complaints a state will receive.

In the survey, a relationship was found between the number of disciplinary actions taken and the percentage of public members on the licensing board. If public members constituted at least 29 percent of the board, the board was more likely to be among the most active states in disciplining dispensers.

Recommendations include having well-publicized and easily accessible consumer complaint procedures. Toll free "800" phone numbers are particularly successful as are requirements that phone numbers be printed at the top of every hearing aid sales contract and be on display in each dispenser's office. Complaints should be investigated within a reasonable time period and after each disciplinary proceeding is completed, a press release should be issued. Also, boards should issue annual reports, detailing the number and nature of complaints received and disciplinary actions taken.

Regulatory Overview

Most consumer products and services are regulated in some manner by a government agency. Hearing aids are no exception, but regulation of this product and of its dispensers is minimal.

The Federal Trade Commission (FTC) took action in the 1970s against six hearing aid companies to stop deceptive claims and practices and proposed a trade regulation rule for the hearing aid industry. After studying the problems for ten years, the FTC declined to adopt comprehensive regulations. Hearing aid sales, however, are covered by general federal and state prohibitions against deceptive acts and practices. Consumers are protected by FTC's right-to-cancel rule, i.e., the "three day cooling off" period, if the hearing aid sale occurs in their home. Consumers may write to the FTC about their hearing aid problems. The FTC has the authority to do case-by-case adjudication but rarely exercises it.

Hearing aids are regulated as medical devices by the Food and Drug Administration (FDA). The FDA sometimes inspects products at the manufacturing stage and oversees pre-market approvals for related devices, such as cochlear implants. The FDA, however, does not monitor the records of hearing aid specialists or dispensers, but in April 1993 did send letters to six manufacturers that violated its regulations on misleading claims. FDA's other regulations include labeling requirements, mandatory medical evaluation of children up to eighteen years of age,² and a

requirement that dispensers refer for professional care any potential client who has acute drainage from the ear, chronic dizziness, pain, and other medical symptoms. Under FDA regulations, all adult first-time buyers are to be informed of their right to obtain a medical evaluation before purchasing a hearing aid. Consumers may waive that right in writing. The FDA held a public hearing in April 1991 concerning Vermont's request to have stricter standards for medical evaluations than the FDA requires. Vermont wants to establish required medical evaluations for groups it determines need special protection, such as retarded persons or senior citizens. The FDA is expected to rule for Vermont.

The Veterans Administration is the single largest purchaser of hearing aids, providing them to veterans with a service-connected hearing loss. The agency has no regulatory authority. However, it tests devices before purchasing them and publishes a technical bulletin detailing the test results and a general information pamphlet for consumers.

Most of the regulation of hearing aid dispensers, thus, takes place through state occupational licensing and consumer protection laws.

Recent Survey of Regulators

In the summer of 1991, the University of Maryland School of Social Work along with the Center for the Study of Responsive Law conducted a mail survey of state hearing aid regulators. The survey was designed to determine how actively state regulatory bodies enforce laws protecting hearing aid customers. A written questionnaire was sent to each hearing aid dispenser licensing board in all 50 states and the District of Columbia. Since not all states have such boards, and some states handle hearing aid consumer concerns in unique ways, another questionnaire was sent to the consumer affairs section of each state's attorney general's (AG) office. This resource brief summarizes the findings of that study.

Responses to the board questionnaire were received from 45 states as of early 1992.³ Follow-up telephone calls were made to clarify responses or to obtain additional information. Arkansas, New York, Rhode Island, and Virginia did not respond and D.C. and Tennessee answered only a few of the questions. A few states, such as Colorado and Massachusetts, do not regulate hearing aid dispensers.

The twenty responses returned by AG's offices helped provide a more complete picture of state regulation. Audiologist and physician licensing boards were not contacted, although some of those professionals also dispense hearing aids. For convenience, D.C. is treated as a state in the text, and all hearing aid sellers who have a formal relationship with their state are referred to as "licensees."

General Regulatory Structure and Process

There is great variation among the states in the location of the hearing aid boards within the state bureaucracy. Boards may be located in departments of professional regulation, health or commerce. Law enforcement functions are handled by one agency in some states and are divided among several agencies in other states.

Each state has its own system for handling complaints. In some states, complaint handling is centralized in the AG's office or the office of consumer affairs. In other states, complaint handling responsibilities are shared by the board, the AG, and the county prosecutor. Given the many different access-redress pathways that exist, addresses and phone numbers for complaint handling offices need to be publicized widely and effectively.

An Overview of Current Licensees and Boards

Each state was asked to indicate the number of hearing aid dispensers it regulates. Figure one shows the number of licensed dispensers in each state during 1990 (see Appendices). Figure two shows the proportion of licensed dispensers in relation to persons age 55 and older in each state.⁴ Such ratios do not take into account geographic location or rural access.

States with boards (or committees or councils that function in similar ways) were asked questions about the function of the regulatory boards, their size, their composition, and the frequency of their meetings. Oregon formed the first hearing aid dispenser licensing board in 1959. The most recently created boards, those in Illinois, Indiana, South Dakota, and Vermont were formed during the 1980s. Florida created an Advisory Council in 1968, but has had a licensing board only since 1983. The smallest board is Nevada's with only three members, and like those in Pennsylvania and South Carolina, it met only once during 1990. The two most active boards, Kansas and New Jersey, met ten times that year.

The survey also inquired into the composition of state boards. Those in Arizona, Delaware, Hawaii, Illinois, and New Mexico have one-third or fewer dispenser members. Hawaii has three public members on its seven member board. Illinois, Iowa, Kansas, and Utah have two out of five public members for a 40% ratio. Arizona, Delaware, Florida, Michigan, Nevada, and West Virginia have boards composed of one-third public members. At the other extreme, Idaho, Nebraska, North Dakota, Ohio, and Wyoming have no public members. In Louisiana, seven of nine members are dispensers; in Alabama, five of seven members are dispensers. Michigan, Nevada, and Missouri also have a high proportion of dispensers as board members.

COMPOSITION OF 39 DISPENSER LICENSING BOARDS

<u>Dealers as % of board</u>		<u>Public Members as % of board</u>		<u>Audiologists, MDs as % of board</u>	
%	# of states	%	# of states	%	# of states
20	1	0	5	0	3
22	1	11	1	11	2
29	1	12	1	14	2
33	2	14	6	20	4
37	1	17	2	22	4
40	4	20	4	25	2
43	4	22	4	29	7
50	5	25	2	33	3
55	5	29	3	37	1
57	4	33	6	40	6
60	6	40	4	43	1
62	1	43	1	44	1
67	2			50	3
71	1				
77	1				

n=39 states

Licensure Requirements

Most states have similar basic requirements for persons dispensing hearing aids: a minimum age (18, 19 or 21), minimum education (high school), and freedom from contagious or infectious disease. Forty states require a written examination, often the industry-prepared examination. Thirty-seven states require some combination of a practical and oral examination. Some states, such as Georgia, require a traineeship, apprenticeship, or supervision by a licensed dispenser. Delaware, Indiana, Pennsylvania,⁵ and Wisconsin require no oral exam.

Thirty-one of the responding states require annual continuing education hours to maintain a license. A few states review a dispenser's testing procedures used to determine hearing loss or calibration of a dispenser's audiometric equipment.

Disciplinary Authority and Action

Thirty-three states require that those who hold licenses to dispense hearing aids must not engage in "unlawful practices" or "prohibited acts." When such prohibited or controlled practices are specified in state law, they may include (a) using fraud or misrepresentation, (b) door-to-door sales, (c) gross negligence while providing hearing aid services, or (d) promoting the sale of goods and services through the use of undue influence or the exploitation of a person for the financial gain of the licensee or a third party.

Forty-three states reported having the following disciplinary authority:

- 39 boards can revoke or suspend licenses
- 28 boards can issue private reprimands

- 26 boards can refuse renewal
- 26 boards can put dealers on probation
- 22 boards can issue public reprimands
- 19 boards can fine.

Except for the power to fine, most boards appear to have sufficient power. The question is how much they use it.

Figure three shows a great variation in the average number of enforcement actions in each state for the years 1988-1990. Figure four shows the average number of actions in relation to the number of dispensers licensed in 1990. The highest rates of disciplinary actions per 1000 licensed dealers occurred in Idaho, New Jersey, Minnesota, Kansas, Florida, and Wyoming. Figure five shows the average number of actions in relation to the number of persons age 55 and over in the state, the primary population purchasing hearing aids. (These three graphs include only those states which supplied three years of data).

Of the thirty-seven states that provided three years of enforcement data, 27% reported no disciplinary actions in the period 1988-1990. These states are: Alaska, Connecticut, Delaware, District of Columbia, Indiana, Maine, Nebraska, Nevada, North Carolina, and North Dakota. Mississippi⁶ and New Mexico, which supplied figures for fewer than three years, also reported no disciplinary actions. In contrast, Arizona reported twenty actions in one year. Two states, Montana and Tennessee, reported they do not maintain records of disciplinary actions.

The eight states with the highest absolute number of enforcement actions are Florida, New Jersey, Idaho, Kansas, Arizona, Michigan, Illinois and Georgia. Of these states, six are among the fourteen states having

the highest proportion, at least 29% or more, of public members sitting on disciplinary boards. The six states which have the highest proportion of public members and have the highest number of enforcement actions are Florida, New Jersey, Kansas, Arizona, Michigan, and Illinois.

Several large states such as California and Texas receive a significant number of complaints, but take an insignificant number of actions. States with 800 numbers receive the most complaints, but do not necessarily take the most disciplinary actions. This occurs in part because some of the calls are requests for information or reports of consumer problems not warranting formal disciplinary action.

A shortage of staff may help explain the small numbers of disciplinary actions. New Mexico reported it has only one investigator for twelve licensing boards. California reported a shortage of investigators and a large backlog of complaints in 1990. The California state medical board's division of allied health professions is responsible for hearing aid dealer investigations. Legislation enacted in 1990 established schedules for investigating complaints and completing disciplinary actions. In 1991, the California board revoked six licenses. While still low for the number of licensees and complaints, the state now may have the power and procedures to be more active.

Complaints to Regulators

Figure six shows the average number of complaints filed with licensing boards per year during 1988-1990, the latest years for which many states had complete data. States reporting the most complaints are California (300), Illinois (296), Florida (204), Texas (159), Minnesota (79), and Pennsylvania (78). The number of complaints appears to correlate with both the population size and the ease of complaining to regulators in a particular state. For example, California, Illinois and Minnesota have 800 phone numbers for the public to use. In Texas the complaint number is on all hearing aid sales contracts and is displayed in all dispensers' offices.

Boards' documentation of the number of complaints, their content, and their source was uneven. The number of complaints to boards ranges from zero to 300 a year. One might question whether states reporting no complaints in actuality received none. In any event, the number of formal complaints received by any governmental office represent only a portion of actual problems.

The most frequent sources of complaints are consumers and other dispensers. Human service providers, law enforcement offices, consumer agencies, and better business bureaus were the next most frequent sources. Doctors were the least common source of complaints in all responding states. Minnesota presented a typical response, estimating that

85% of their complaints were from consumers and their families, 5% from other sellers, 5% from attorneys and legal advocacy services, 3% from human service providers, and 2% from physicians.

A total of forty-three states provided details about the content of their complaints. In descending order of frequency, complaints concerned refunds and advertising, poor fit, improper functioning of the device, trial periods, prices, and sales techniques. Other complaints involved repair problems, warranties, insurance misinformation, lack of follow-up service, the presence of an unidentified medical condition, mislabeling, unclear contracts, non-delivery of a device, and unlicensed vendors. Several states wrote that a major cause of complaints is the advertising hyperbole that gives consumers unrealistic expectations of what a hearing aid can do. These states suggested that advertising claims be controlled and consumers be better educated.

North Carolina's board reported that most complaints repeatedly concern the same hearing aid dispensers who all work for the same company. Similarly, the Connecticut AG's office had five complaints in 1990 about problems with refunds owed by the same franchise of one company.

Consumer Remedies

Like most licensing boards, hearing aid dealer boards may discipline dispensers, but are not empowered to order refunds or other restitution for a consumer. Thus, it is not unusual for a board to hold a hearing, revoke a license, and then send the case to the AG's office to obtain refunds. For example, although New Mexico's board took no enforcement actions in 1990, the AG's office obtained \$8,000 in refunds as a result of action on twelve complaints.

Surety bonds can protect consumers against default and fraud, but do nothing to protect against incompetence. Illinois, Missouri, and Washington require dispensers to be bonded. A bond increases the likelihood of redress, although it is not automatically available.⁷ Surety bonds are expensive and few companies sell them. Minnesota and Alaska recently repealed their bonding requirements.

In some states, laws or regulations require a 30-day trial period with the right to cancel and receive a refund (minus a reasonable fitting charge) if the consumer returns the aid. Vermont has mandated a 45-day trial period. Some dispensers refuse to cancel sales, accept returns, and make refunds after the trial period has expired. Consumers may look to state government to put pressure on the seller, mediate, or enforce the law and order a refund. For example, in 1990 Indiana's Attorney General had fourteen complaints about refund problems and seven about incorrect billing.

Conclusion

The survey suggests several ways in which hearing aid dispenser licensing boards could become more active in consumer protection. First, boards can do more to educate the public about the board's powers and authority, so consumers know what complaints to file with a licensing board and what complaints to take to another authority. When boards receive complaints that are beyond their jurisdiction, they should refer the complainant to the appropriate government agency.

Complaints should be used as part of a state's monitoring process. Even when they do not result in penalties, complaints indicate how regulation and consumer education could be improved. When violations do occur, investigation and discipline should be expeditious.

Many states take very few enforcement actions against licensees. Our study suggests that when public representatives constitute 29% or more of a board's members, the state is more likely to be active in disciplining licensees. An earlier study of occupational boards showed that "increased proportions of public members are associated with more serious disciplinary actions."⁶ All board members would benefit from regular interaction with consumer organizations, hearing aid users, disability rights groups, providers, and state legislative oversight committees.

Licensees and boards must be held accountable. This study reveals a need for boards to keep better records of their basic operations and collect information that can form the basis for improvements in regulatory and administrative procedures and in the quality of hearing health care.

SPECIFIC RECOMMENDATIONS TO BOARDS

1. Be sure offices responsible for receiving consumer complaints are well publicized and easily accessible to the public by telephone.

Although all states may ultimately need to receive a letter and documentation to process a complaint, states that take complaints informally by phone encourage consumers to come forth. States receiving the most complaints have widely publicized phone numbers. Some states use 800 numbers while others require their address and phone number on hearing aid sales agreements or in dispensers' offices. Some respondents commented that they receive many telephone complaints, but their requirement of written complaints results in a significant decrease in complaints actually filed. If agency staff were available to help consumers put their complaints in writing, more investigations could take place.

2. Hearing aid complaints should be investigated and disciplinary action should be taken within a reasonable time.

Many respondents commented that they share investigative staff with agencies that investigate medical or other occupational complaints. For many reasons, hearing aid complaints are deferred and even ignored. If necessary, states should establish time limits for completing investigations. Keeping careful records of all complaints makes it possible to detect patterns of conduct that might lead to discipline.

3. Basic information about board operations should be released annually to the public. These reports should include the number and nature of complaints received and disciplinary actions taken.

Several states were unable to answer the most basic questions about their annual operations, such as the number of complaints received, the number of disciplinary actions taken, or the number of times the board met. Some explained that the lack of basic records is due to staff shortages or negligence. Regardless of the reason, the result is unacceptable and easily corrected without great expense.

4. Whenever a disciplinary proceeding is concluded, a press release should be issued providing complete information about the offense and the penalty imposed.

Such information educates the public about the board's role in consumer protection and what are unacceptable practices by hearing aid sellers.

5. Public representatives should comprise 30 percent or more of a board's membership to help ensure that a state is able to effectively protect consumers from dispensers' illegal actions.

One-third appears to constitute a sufficient critical mass of independent members for the board to overcome the traditional dominance of the occupation. Public members must understand their role, receive adequate training and orientation, and be included in all decision making.

FOR COPY OF QUESTIONNAIRE, DETAILS ABOUT INDIVIDUAL STATES, EXAMPLES OF REGULATORY AND ADMINISTRATIVE PRACTICES HELPFUL TO HEARING AID CONSUMERS, AND SOURCES OF CONSUMER INFORMATION ON HEARING AIDS, READERS MAY SEND FOR THE ORIGINAL STUDY BY CONTACTING EITHER OF THE AUTHORS.

*Hearing Aid Dispenser State Licensing Boards:
Report of a National Survey*

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Endnotes

1. "Licensure of Hearing Aid Dispensers: Review of Statutory 'Sunrise' Factors" (undated paper, Office of the Attorney General, State of Vermont).
2. Children must see a physician to eliminate a medical cause for hearing loss before their first aids are purchased and an audiologist for evaluation and rehabilitation. This requirement may not be waived.
3. Most states attached copies of their state laws as requested.
4. Wyoming, Montana and Maine have more dispensers available for older consumers than do Alaska, Hawaii and Minnesota.
5. Pennsylvania distinguishes between dealers and fitters; fitters work for dealers and each takes a different exam.
6. Mississippi only had data from October 1989 forward.
7. Particularly if many consumers are involved.
8. E. Grady and M. Nickol, "Structural Reforms and Licensing Board Performance," *American Politics Quarterly*, 18, 3, (July 1990): 382.

Figure 1

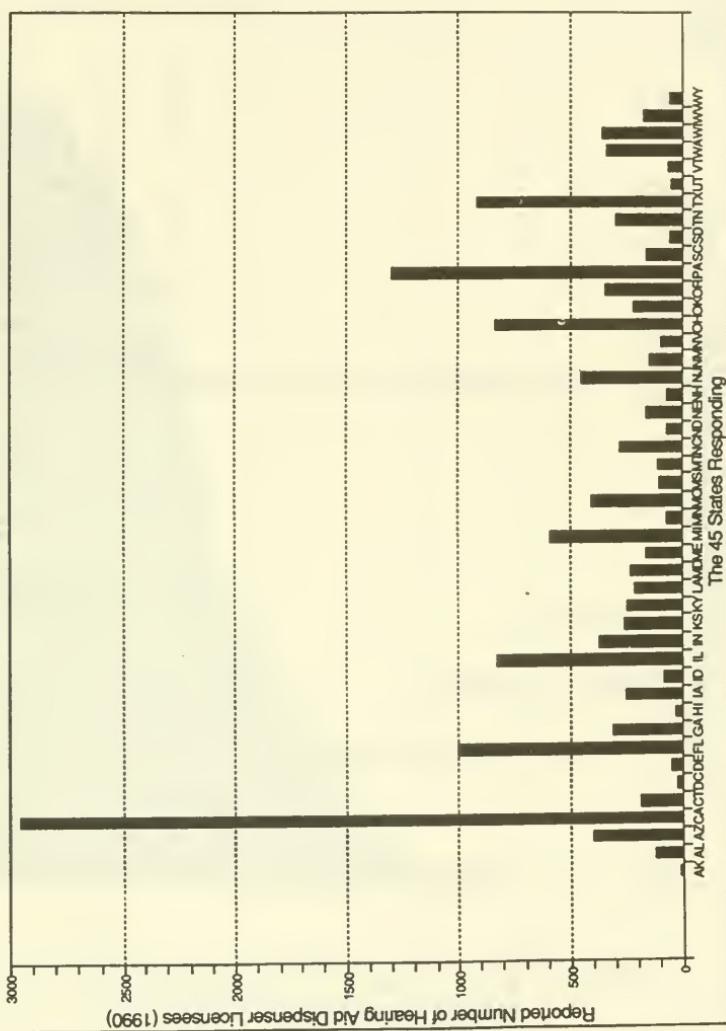


Figure 2

Licenses per 1000 Persons Age 55 and Over

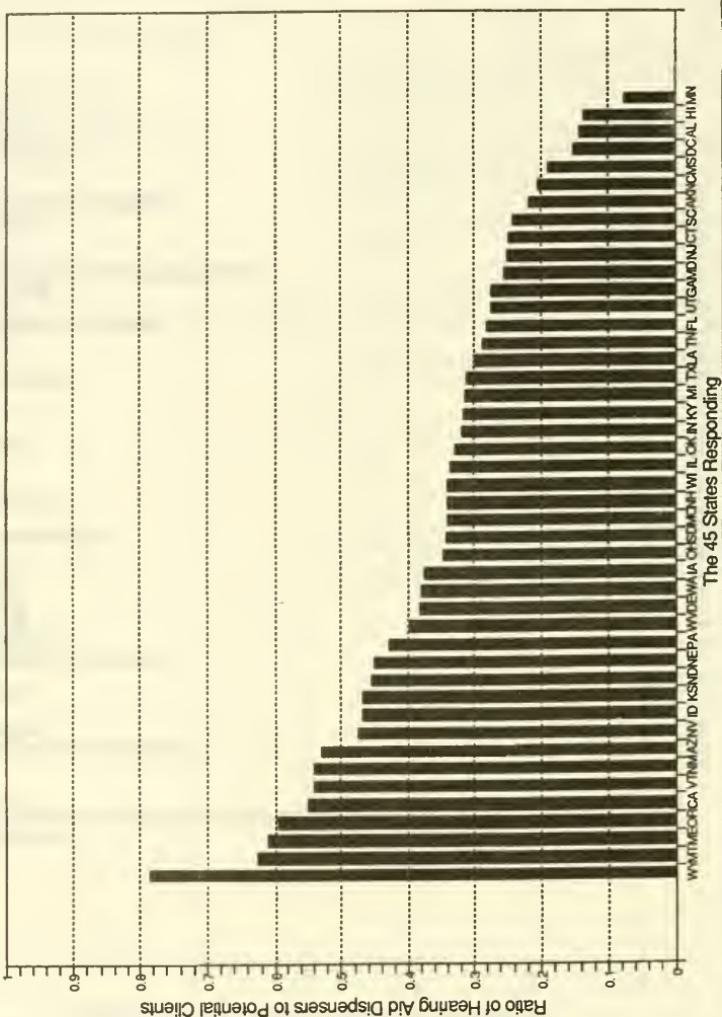


Figure 3

Average Number of Disciplinary Actions per Year
By State Regulators of Hearing Aid Dispensers

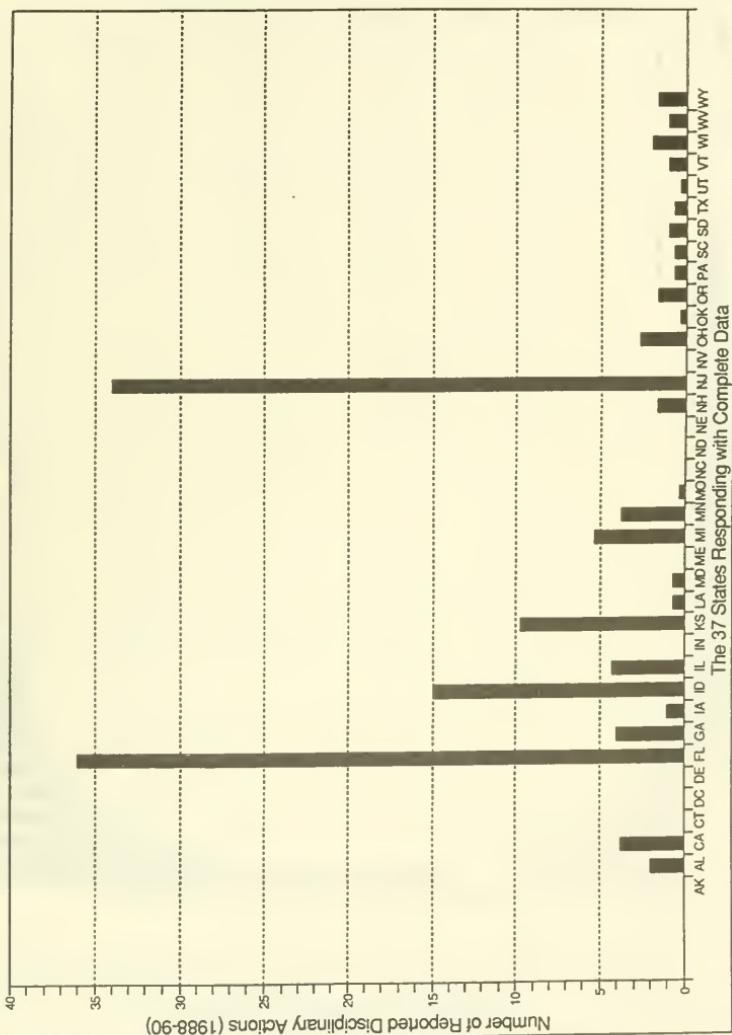
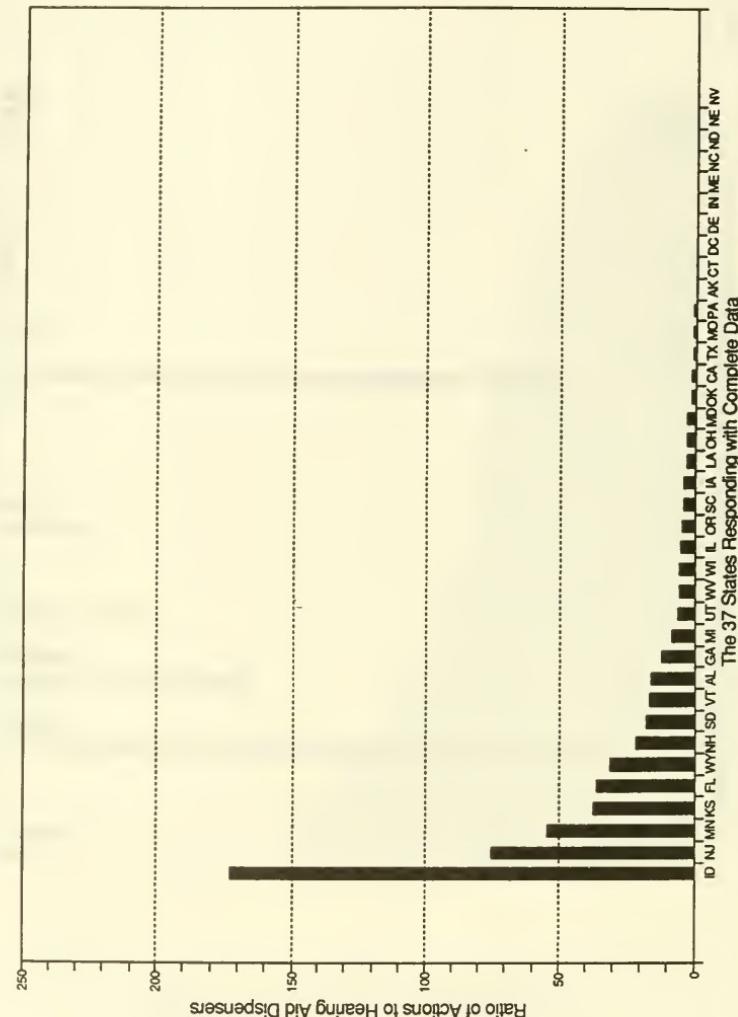


Figure 4

Disciplinary Actions per 1000 Dispensers



Disciplinary Actions per 100,000 Persons Age 55 and Over

Figure 5

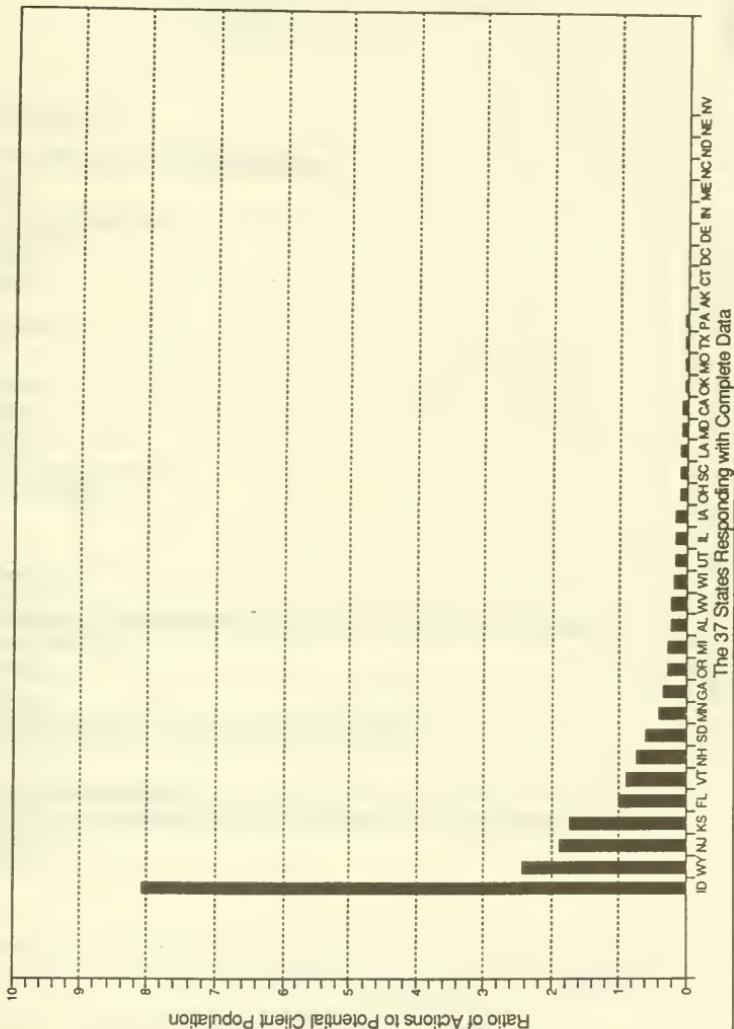
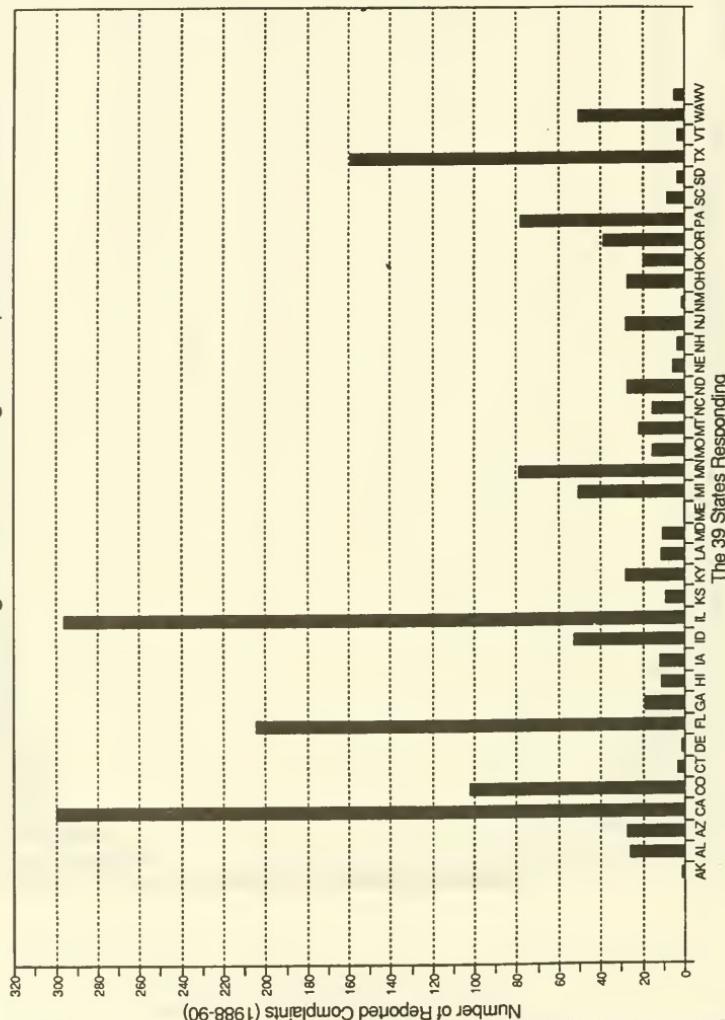


Figure 6

Average Number of Complaints per Year
To State Regulators of Hearing Aid Dispensers



STATEMENT BY ARTHUR J. GRELES
TO THE SENATE SPECIAL COMMITTEE ON AGING
SEPTEMBER 15, 1993

MR. CHAIRMAN: My name is Arthur J. Greles and am presently employed as Information Systems Director to Senator Paul Simon of Illinois. I am also an active member of Self Help for Hard of Hearing People, Inc. (SHHH).

I have been asked by the Committee to submit written testimony regarding my experience with hearing loss and the purchase of hearing aids. In 1991, I suffered a severe brain injury and hemorrhage resulting in permanent severe sensorineural hearing loss. Prior to this injury, I had normal hearing.

After a successful recovery and outpatient rehabilitation, I was referred to a prominent Ear, Nose and Throat physicians' group in the Washington metro area for treatment of the ear and hearing damage. After successful treatments for removal of blood clots remaining in my right ear, I submitted to 4 complete audiograms and was recommended and fitted for a canal-type hearing aid at a cost of \$650, plus the audiogram charges and a hearing-aid consultation fee. This was all arranged through the physician's office and audiologist.

Since I was brand new at purchasing and using hearing aids, I really had no idea what to expect or what kinds of questions to ask. As it turned out, this hearing aid eventually proved ineffective because my hearing level had changed and it was not adjustable and did not come with a telephone switch ("T-switch"). A T-switch is needed to use both permanent and portable FM audio loops which enhance the hearing-impaired person's sound through magnetic induction. I did not even know that T-switches existed, let alone to be sure I asked for one. This information should have been provided by the physician-dispensing office. I only discovered these facts through my membership with SHHH when I went to them for help.

I then was referred to another hearing aid dispenser and purchased a behind-the-ear hearing aid which is flexibly adjustable to hearing level changes and also has the "T-switch." This new hearing aid has worked fine for me ever since. The bottom line is that I now have an old hearing aid that is kept in my bedroom drawer at home at a cost of over \$1,000.

It is also important to note that during this period, I had experienced further bleeding, discharge and pain in my ears. I telephoned the Ear, Nose and Throat physicians' group and they told me they could not see me for five days because they were too busy. I then reported this to my general physician who saw me immediately and treated me for a ruptured eardrum. I have no further contact with the Ear, Nose and Throat group.

I want to further state for the record how important and valuable Self Help for Hard of Hearing People, Inc. was for me during this difficult and frightening experience. Through its local chapters and national organization, SHHH continues to provide information, support and education about hearing loss not only to the Hard of Hearing community, but to the general public at large. We need to ask more informed and intelligent questions when purchasing all hearing assistive devices. SHHH has helped to make the possible.

I am relating this experience for all in the hearing-impaired community and hearing care specialists to learn and to prevent this kind of abuse and negligence. We are concerned consumers and citizens and our voices must be heard.

Thank you very much.

HEARING CARE SERVICES AND HEALTH CARE REFORM

Prepared for the
President's Task Force on National Health Reform

American Academy of Audiology
April 29, 1993

The American Academy of Audiology is pleased to supply the attached information to aid in the deliberations of the important issues confronting the delivery of health care services in the United States. We feel this information can further serve to reduce costs and increase accessibility of the American public to health care in general, and hearing care in particular.

Representatives of the American Academy of Audiology stand ready to meet or discuss the propositions contained herein. The offices of the American Academy of Audiology are located in Washington and can be reached by phone at (202) 687-6997. Lucille Beck, Ph.D., President-Elect of the American Academy of Audiology, is also located in Washington, D.C. at the Department of Veteran's Affairs Medical Center. She can be contacted at (202) 745-8270.

The membership of the American Academy of Audiology would like to thank you for the time and energy in considering this information. Please feel free to contact the Academy if we can answer any questions or supply further information.

The American Academy of Audiology

Submitted by:
Thomas J. O'Toole, EdD
President,
American Speech-Language-
Hearing Association
September 15, 1993

STATEMENT AND NARRATIVE**HEARING CARE SERVICES
AND
HEALTH CARE REFORM****STATEMENT OF THE AMERICAN ACADEMY OF AUDIOLOGY:
HEARING CARE SERVICES AND HEALTH CARE REFORM**

The American Academy of Audiology believes the issues of cost containment and accessibility to health care in general, and hearing care specifically, can be addressed, in part, by consideration of the methods by which services are delivered to the American people. The traditional physician-driven model of health care fails to adequately recognize the role or responsibility of the non-physician provider, regardless of the training, expertise, costs savings, or accessibility to services available through these professions. Audiologists are qualified through education and training to provide hearing care services. Delivery of hearing care services by audiologists can result in lowered costs and increased accessibility without sacrifice of quality. The American Academy of Audiology believes that cost containment of and accessibility to hearing care can also be served by: (1) further expanding the role of audiologists as entry points into the hearing care system, and (2) ensuring the role of audiologists as hearing service providers through appropriate state and federal legislation. The American Academy of Audiology also recognizes it's responsibility to educate the public regarding the expertise and role of audiologists in the provision of hearing care services.

NARRATIVE

The American public has grown to believe that health care is synonymous with physicians and hospitals. The provision of health care services, in a global sense, includes many non-physician providers including Nurses, Optometrists, Dentists, Podiatrists, Occupational Therapists, Physical Therapists, Psychologists, and others. In many of these examples the non-physician health care provider is the entry point to the service they provide. A similar example is the audiologist who is the specialist trained to provide hearing care services. Audiologists are state-licensed practitioners who work independently within the health care system. Many federal mandates call upon the audiology profession for the provision of hearing care services within the community. However, utilization of audiological resources, that ultimately result in lowered costs and increased accessibility, have been restricted due to lack of appropriate legislative recognition by the federal government along

with continued barriers and unwarranted restrictions on the part of the historical physician-driven system. The American Academy of Audiology believes that cost containment and accessibility to hearing care can best be served by recognizing the expertise available through the audiologist; and by endorsing audiologists as one of the entry points into the hearing care system.

MANDATES FOR AUDIOLOGIC SERVICES

The necessity to expand the concept of health care in general, and hearing care specifically, beyond the historical physician-driven systems, does stems not only from the opinions of the membership of the American Academy of Audiology but is mandated by programs and laws of the federal government, including the U.S. Public Health Service and the National Institutes of Health, the Department of Veteran's Affairs, the Department of Labor and the Occupational Safety and Health Administration, and Public Laws 92-142 and 99-457. Examples of the services provided by audiologists are listed in the report Healthy People 2000, issued by the U.S. Public Health Service. The objectives of this report include reduction of the proportion of workers exposed to excessive daily noise levels (section 10.7), reduction of significant hearing impairment (Section 17.6), an increase in the proportion of primary providers who refer children and older adults for screening and/or assessment of hearing loss (Section 17.15), reduction in the average age of identification of hearing loss to less than 12 months (Section 17.16), and reduction of the number of days of school absenteeism due to middle ear infections (Section 20.9). The 1983 Hearing Conservation Amendment to the Noise Control Act (29 CFR 1910.95) (Attachment A), mandates hearing conservation programs, under the direction of audiologists or appropriately trained physicians, to persons exposed to excessive levels of noise in the workplace. The U.S. military has adopted the Hearing Conservation Amendment guidelines to protect the hearing of servicemen and women, and are implemented under the direction of audiologists. Public Laws 99-457 and 94-142 both address the educational needs of the handicapped, including the hearing impaired and deaf, and include provisions for audiological services.

The National Institute on Deafness and Other Communicative Disorders recently proposed that all children born in the United States be screened for hearing loss (Attachment B). In addition, the Joint Committee on Infant Hearing, represented by members of the American Academy of Pediatrics, the American Academy of Otolaryngology, and the American Speech Language Hearing Association, issued a policy statement specifying the need for hearing testing in newborns and infants at risk for hearing loss, and that the screening be conducted under the supervision of an audiologist (Attachment C). The American Academy of Pediatrics recommends referral for audiometry for children with a history of ear infections (Attachment D). The American Academy of Audiology recommends an aggressive posture for the identification and remediation of hearing loss in the aged population particularly with the expected significant increase in this population over the next decade (Attachment E).

ROLE AND SCOPE OF AUDIOLOGIC PRACTICE

The services and programs currently provided by audiologists include the assessment of hearing, determination of hearing levels in the newborn and infant, screening and hearing assessment in both public and private schools, determination of the cause and location of hearing loss, evaluation and fitting of hearing aids and other assistive listening devices, assessment of balance and vestibular disorders, monitoring of the auditory system during surgical procedures, management of hearing conservation programs in industry and the military, and development and implementation of rehabilitative programs for the deaf and hearing impaired (Attachment F). Audiologic practice settings include private and government (Veteran's Administration) hospitals, physician practices, the military, public and private schools, and independent private practice. Audiologists are licensed in 42 states (pending in others) as independent providers of hearing care services.

The American Academy of Audiology represents more than 5000 audiology practitioners in the United States. Founded in 1988, the AAA is dedicated to the continued improvement of hearing care services and programs offered to the American public. Members of the AAA subscribe to a Code of Ethics which requires honesty, compassion and competence in the delivery of hearing care services (Attachment G).

PROVIDERS OF HEARING CARE

Two primary groups of academically trained specialists are involved in the provision of hearing care services: the Audiologist and the Otologist. Each has different training, expertise and means by which to serve the hearing care needs of the public. A third group, hearing aid dispensers, are not academically trained.

Currently, there are about 10,000 audiologists in the United States. Audiologic training generally consists of completion of a prescribed program of study, including both didactic coursework and practical experience, culminating in a graduate or professional degree from an accredited University, passing of a comprehensive national examination, and completion of one year of practical experience beyond graduate school. Coursework includes anatomy, physiology and pathology of the auditory system, basic and advanced assessment techniques of hearing evaluation including the electrophysiologic evaluation of the auditory system, techniques in the assessment of the vestibular (balance) system, evaluation, fitting and dispensing of hearing aids or other assistive listening devices, special techniques to evaluate the pediatric population, methods of hearing conservation including those mandated by the government, acoustics and speech perception, normal and abnormal speech and language development, and intervention and rehabilitation programs for the deaf and hearing impaired. Practical experience with children and adults, in a variety of settings, is required prior to graduation. To be a licensed practitioner also requires the passing of a national examination and the completion of one year of supervised experience following graduation.

Currently, programs of study in Audiology are being revised to reflect a greater commitment to education prior to graduation (Attachment H).

The primary medical specialty serving hearing care is Otology, a sub-specialty of Otolaryngology (Ear, Nose and Throat). This is a surgical specialty with residency training programs focused on the development of surgical skills, including those associated with the surgical treatment of hearing loss. Otolaryngology residents receive lectures and exposure on hearing assessment, hearing conservation programs, and non-medical treatment of hearing loss with hearing aids and other assistive listening devices. The majority of the instruction on assessment of hearing loss and non-surgical treatment options is taught by audiologists. Actual coursework, lectures and practical experience in hearing assessment is significantly less than that which occurs during the training of an audiologist. In fact, a prominent otolaryngologist recently intimated the unsatisfactory nature of contemporary otologic training programs (Attachment I), particularly in understanding the areas of auditory theory, hearing assessment, communication development, educational programs for the deaf and hearing impaired and hearing aid technology and experience. These areas, however, have been part of audiology training for more than 20 years. Based on these observations, and the instructional programs currently afforded to otolaryngology residents and medical students by audiologists, a strong argument for the recognition of the audiologist as the expert in hearing care can be made.

The practice of the hearing aid dispenser is restricted to the evaluation and fitting of hearing aids. Assessment or management is limited to a basic hearing evaluation related to the hearing aid sale. Hearing aid dispensers are not required to have a college education, or any formal didactic training from an accredited university or training program, but must meet the requirements for state licensure. In some states, educational requirements include a high school education, a supervised work experience and the passing of an qualifying examination developed by audiologists or based upon textbooks authored by audiologists. The primary focus of the hearing aid dispenser is the sale of hearing aids. The American Association of Retired Persons, in its report on hearing aids, recommends to its members that they get a hearing evaluation from an audiologist before buying a hearing aid. The majority of Audiologists also dispense hearing aids under the appropriate license.

SERVICE DELIVERY: COST CONTAINMENT AND ACCESSIBILITY

Access to hearing care services currently occurs through multiple entry points, including primary care physicians (pediatricians, internal medicine, family practice) Otolaryngologists, Audiologists and hearing aid dispensers. Typically, the patient with a medically or surgically treatable hearing loss is referred to the otolaryngologist. A hearing

loss not requiring treatment by medical or surgical means can be referred directly to the audiologist for management with hearing aids or other assistive devices. Unfortunately, patients seen by primary care specialists are often referred only to the otolaryngologist for further evaluation, even if the complaint is simply hearing loss. Since the incidence of treatable ear disease in persons complaining of ear or hearing problems is low (Goldstein, 1984), costs of hearing care could be substantially lowered and patients better be served by direct referral to the audiologist. Services conducted through physicians offices show increased utilization and increased charges per patient when the services are "owned" by the physicians (Mitchell and Scott, 1992).

The provision of professional hearing care services has a direct parallel in vision care (Attachment J). The relationship between the optometrist and ophthalmologist is similar to the relationship between the audiologist and the otolaryngologists. Optometrists are recognized, both by the public and the government as important providers of specialty care. Although the ophthalmologist serves as the medical specialist, the optometrist provides an entry point that serves to evaluate visual acuity, refer for medical treatment if indicated, dispense corrective prostheses and provide visual training. Similarly, Otolaryngologists serve as the specialist trained in the surgical correction of hearing loss while audiologists are trained to evaluate hearing, refer for medical treatment if necessary, and provide non-medical corrective techniques.

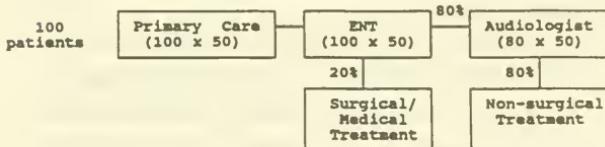
Although systematic studies of the potential cost savings from utilization of the audiologist as entry level providers have not been completed, information from the vision care area shows that the non-physician professional, i.e. the optometrist, provides services at lower costs and with greater access to services. Fees for comparable services were lower when provided by optometrists than when provided by ophthalmologists, and patients could be seen sooner by the optometrists (Soroka, 1991). While physicians generally object to direct-access to non-physician providers, numerous studies demonstrate support and confidence, on the part of patients, for direct-access to non-physician providers (e.g. Domholdt and Durchholz, 1992; Durant, et al., 1989). Therefore, the optometrist serves an important role in vision care by providing increased accessibility through lower costs but without sacrificing quality. Expanding the role of the audiologist in the provision of hearing care would also result in greater accessibility, reduced cost, and with no sacrifice in quality of services provided. The freedom to serve as an entry point into health care, similar to that provided by the optometrist, expands the choices of the American public, results in competition thus further lowering costs, and increases accessibility through the lowered costs and increased number of providers.

The following flowcharts illustrate the potential cost reductions afforded by restructuring the delivery of hearing care in a manner consistent with that for vision care:

The flowcharts are based on the following assumptions:

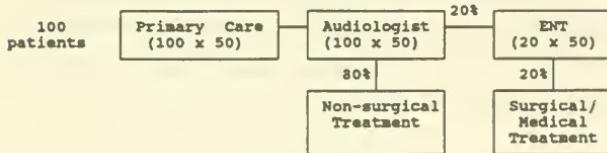
1. Charges in units not dollars
2. Equal unit charges per specialty (50/visit)
3. 80% of all hearing losses not treatable by surgical/medical means
4. ENT will refer for hearing evaluation in 80% of the cases seen
5. 100 patients

I. PRIMARY CARE AS ENTRY; Automatic referral to ENT



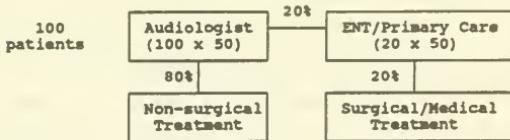
TOTAL COST: $(100 \times 50) + (100 \times 50) + (80 \times 50) = 14,000$ units

II. PRIMARY CARE AS ENTRY; Referral to Audiology



TOTAL COST: $(100 \times 50) + (100 \times 50) + (20 \times 50) = 11,000$ units

III. AUDIOLOGIST AS ENTRY; Referral to ENT/Primary Care



TOTAL COST: $(100 \times 50) + (20 \times 50) = 6,000$ units

SUMMARY AND RECOMMENDATIONS

Accessibility and cost reduction in hearing care specifically, and health care in general, can be addressed, in part, by modification of the service delivery system. Although direct access to hearing care services provided by audiologists is available, it is significantly under-utilized. Although numerous causes for this under-utilization could be identified, two important reasons are evident. First, the traditional physician driven model of health care places undue and unwarranted emphasis on the physician provider and fails to adequately recognize the expertise and services available through non-physician providers, including audiologists. Second, the lack of appropriate legislation that provides for professional recognition by agencies such as the Health Care Finance Administration and Medicare, and subsequently other third party payors. This in turn restricts options for utilization of audiological services within the health care system.

The following recommendations will allow for increased utilization of audiological and hearing care services, thereby lowering costs and increasing accessibility, yet providing the quality services expected by the American public:

1. The development and implementation of legislation that provides appropriate recognition of audiology as an entry point into hearing care.
2. The development and implementation of legislation that ensures appropriate service provider status for audiologists.
3. The development and implementation of legislation that prohibits any unjustified action to limit the practice of audiology on the part of physician providers.

The American Academy of Audiology recognizes its responsibility to actively participate in the development of better hearing care services to the American people. As such, the AAA has a responsibility to participate in the education of the public, including education as to the scope, quality, accessibility, and affordability of audiological services.

The American Academy of Audiology respectfully requests consideration of the proposals contained herein, and stands ready to meet with the members of the President's Task Force on Health Reform, or other appropriate persons or agencies, to further explain or justify these proposals.

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ATTACHMENTS

ATTACHMENT A: Hearing Conservation Amendment to the Noise Control Act of 1973.
29 CFR 1910, 1983

ATTACHMENT B: Statement from the Consensus Conference on Early Identification of Hearing Impairment in Infants and Young Children. Sponsored by the National Institute on Deafness and Other Communicative Disorders, National Institutes of Health

ATTACHMENT C: Joint Committee on Infant Hearing 1990 Position Statement, American Academy of Pediatrics, American Academy of Otolaryngology, American Speech-Language-Hearing Association

ATTACHMENT D: Statement on Middle Ear Disease and Language Development, American Academy of Pediatrics

ATTACHMENT E: Position Statement: Task Force on Hearing Impairment in Aged People, American Academy of Audiology

ATTACHMENT F: Scope of Practice Document, American Academy of Audiology

ATTACHMENT G: Code of Ethics Document, American Academy of Audiology

ATTACHMENT H: Position Paper: The American Academy of Audiology and the Professional Doctorate (Au.D.), American Academy of Audiology

ATTACHMENT I: William House, M.D., Presidential Address, American Otological Society, American Journal of Otology

ATTACHMENT J: Hearing Care / Vision Care Parallelism in 1991, Table 1: Comments submitted to the Food and Drug Administration, 1991. American Academy of Audiology

ATTACHMENT A

**Hearing Conservation Amendment
to the Noise Control Act of 1973
29 CFR 1910, 1983**

A-1

**Tuesday
March 8, 1983**

federal register

Part II

Department of Labor

**Occupational Safety and Health
Administration**

**Occupational Noise Exposure; Hearing
Conservation Amendment; Final Rule**

Paragraphs (i) (3), (4) and (5)

Paragraphs (j) (1), (2) and (4)

Paragraph (k)

Paragraph (l)

Paragraphs (m) (2), (3), (4) and (5)

Paragraph (n)

Appendices A, B, C, D, E, H and I

Portions of the original hearing conservation amendment were stayed beyond August 22, 1981, and were the subject of this rulemaking. In addition, some provisions which went into effect on August 22, 1981, are also being modified by this final rule. The provisions being issued today in final form will be effective on April 7, 1983, to allow employers enough time to familiarize themselves with the revisions. Table II below lists the provisions and modified provisions (as indicated) which will be effective April 7, 1983.

Table II

Provisions Which Are Effective April 7, 1983

Paragraph (c)(2)

*Paragraph (d)(1)

Paragraphs (d)(1)(i) and (ii)

Paragraph (d)(2)(ii)

Paragraphs (d)(3)(i) and (ii)

Paragraph (e)

*Paragraph (f)

*Paragraph (g)(1)

*Paragraph (g)(3)(i)

Paragraph (g)(3)(ii)

*Paragraph (g)(5)(iii)

Paragraph (g)(5)(iv)

*Paragraph (g)(7)(i)

Paragraph (g)(7)(ii)

*Paragraph (g)(7)(iii)

*Paragraph (g)(7)(iv)

*Paragraph (g)(8)(i)

Paragraph (g)(8)(ii)

*Paragraph (g)(8)(iii)

Paragraphs (g)(8)(ii) and (D)

Paragraph (g)(8)(iii)

Paragraph (g)(9)

Paragraph (g)(10)

*Paragraph (h)(2)

*Paragraph (h)(5)(i) and (ii)

Paragraphs (i)(2)(ii)

Paragraph (i)(2)(ii)(A)

*Paragraph (i)(2)(ii)(B)

*Paragraph (j)(3)

*Paragraph (m)(1)

Paragraph (n)

Appendix F (from January 18, 1981)

Appendix G

*An asterisk denotes those provisions

which are amendments of provisions that

were effective August 22, 1981.

Initially, employers were allowed until August 22, 1982, to complete baseline audiograms. OSHA received a number of requests for extensions of the time allowed to obtain baseline audiograms. Some commenters indicated that they needed more time to comply for various practical and resource reasons (Ex. 329-3; Exh. 327-108). Others stated that OSHA's final decisions on critical technical issues were necessary before baseline

audiograms could be obtained (Exh. 327-88; Tr. Vol. IV, p. 202, March 28, 1982.) One commenter stated that an extension of time to obtain baseline audiograms would avoid the paperwork of asking for a variance (Ex. 329-3). OSHA agrees that an extension of time in which to obtain employee audiograms of approximately one year is appropriate under the circumstances of this proceeding. A number of important elements of the audiometric testing provisions have been reconsidered and revised. Employers could not have performed baseline audiograms until these issues were resolved. Employers now need sufficient time to incorporate these requirements into their hearing conservation programs and to purchase the necessary equipment to run such a testing program or to make the necessary arrangements for consultants to perform these services. In the January 1981 amendments, OSHA allowed approximately one year from the effective date of the standard for employers to obtain baseline audiograms. Since a number of elements related to the baseline audiogram were stayed, OSHA will extend the date for completion of baseline audiograms until March 1, 1984, which is approximately one year after the publication of this document.¹¹

List of Subjects in 29 CFR Part 1910

Occupational safety and health.

Authority: This document was prepared under the direction of Thorne G. Auchter, Assistant Secretary of Labor for Occupational Safety and Health, 200 Constitution Avenue, N.W., Washington, D.C. 20210.

Pursuant to sections 6(b) and 8(c) of the Occupational Safety and Health Act of 1970 (64 Stat. 1562, 1599; 29 U.S.C. 655, 657); Secretary of Labor's Order No. 8-78 (41 FR 25059) and 29 CFR Part 1910, § 1910.55 of 29 CFR Part 1910 is amended as set forth below.

[Sects. 4, 6, 8, 84 Stat. 1562, 1592, 1598, 29 U.S.C. 655, 657; 5 U.S.C. 553; Secretary of Labor's Order No. 8-78 (41 FR 25059)]

Signed at Washington, D.C. this 28th day of February 1983.

Thorne G. Auchter,

Assistant Secretary of Labor.

PART 1910—[AMENDED]

Paragraphs (c) through (p) and Appendices A through I of 29 CFR 1910.55 are revised to read as follows:

¹¹ It should be noted, however, that this delayed effective date is not in addition to the amount of time employers are normally given to obtain baseline audiograms under paragraph (g)(5)(vi). Thus, all current employees must have baseline audiograms taken by March 1, 1984, or six months from the date of their first exposure at or above the action level, whichever is longer.

§ 1910.55 Occupational noise exposure.

(c) Hearing conservation program. (1) The employer shall administer a continuing, effective hearing conservation program as described in paragraphs (c) through (o) of this section, whenever employee noise exposures equal or exceed an 8-hour time-weighted average sound level (TWA) of 85 decibels measured on the A scale [slow response] or, equivalently, a dose of fifty percent. For purposes of the hearing conservation program, employee noise exposures shall be computed in accordance with Appendix A and Table G-16a, and without regard to any attenuation provided by the use of personal protective equipment.

(2) For purposes of paragraphs (c) through (n) of this section, an 8-hour time-weighted average of 85 decibels or a dose of fifty percent shall also be referred to as the action level.

(d) Monitoring. (1) When information indicates that any employee's exposure may equal or exceed an 8-hour time-weighted average of 85 decibels, the employer shall develop and implement a monitoring program. (i) The sampling strategy shall be designed to identify employees for inclusion in the hearing conservation program and to enable the proper selection of hearing protectors.

(ii) Where circumstances such as high worker mobility, significant variations in sound level, or a significant component of impulse noise make area monitoring generally inappropriate, the employer shall use representative personal sampling to comply with the monitoring requirements of this paragraph unless the employer can show that area sampling produces equivalent results.

(2)(i) All continuous, intermittent and impulsive sound levels from 80 decibels to 130 decibels shall be integrated into the noise measurements.

(ii) Instruments used to measure employee noise exposure shall be calibrated to ensure measurement accuracy.

(3) Monitoring shall be repeated whenever a change in production, process, equipment or controls increases noise exposures to the extent that:

(i) Additional employees may be exposed at or above the action level; or

(ii) The attenuation provided by hearing protectors being used by employees may be rendered inadequate to meet the requirements of paragraph (j) of this section.

(e) Employee notification. The employer shall notify each employee exposed at or above an 8-hour time-weighted average of 85 decibels of the results of the monitoring.

(f) *Observation of monitoring.* The employer shall provide affected employees or their representatives with an opportunity to observe any noise measurement conducted pursuant to this section.

(g) *Audiometric testing program.* (1) The employer shall establish and maintain an audiometric testing program as provided in this paragraph by making audiometric testing available to all employees whose exposures equal or exceed an 8-hour time-weighted average of 85 decibels.

(2) The program shall be provided at no cost to employees.

(3) Audiometric tests shall be performed by a licensed or certified audiologist, otolaryngologist, or other physician, or by a technician who is certified by the Council of Accreditation in Occupational Hearing Conservation, or who has satisfactorily demonstrated competence in administering audiometric examinations, obtaining valid audiograms, and properly using, maintaining and checking calibration and proper functioning of the audiometers being used. A technician who operates microprocessor audiometers does not need to be certified. A technician who performs audiometric tests must be responsible to an audiologist, otolaryngologist or physician.

(4) All audiograms obtained pursuant to this section shall meet the requirements of Appendix C:

Audiometric Measuring Instruments.

(5) *Baseline audiogram.* (i) Within 6 months of an employee's first exposure at or above the action level, the employer shall establish a valid baseline audiogram against which subsequent audiograms can be compared.

(ii) *Mobile test van exception.* Where mobile test vans are used to meet the audiometric testing obligation, the employer shall obtain a valid baseline audiogram within 1 year of an employee's first exposure at or above the action level. Where baseline audiograms are obtained more than 6 months after the employee's first exposure at or above the action level, employees shall wear hearing protectors for any period exceeding six months after first exposure until the baseline audiogram is obtained.

(iii) *Testing to establish a baseline audiogram.* shall be preceded by at least 14 hours without exposure to workplace noise. Hearing protectors may be used as a substitute for the requirement that baseline audiograms be preceded by 14 hours without exposure to workplace noise.

(iv) The employer shall notify employees of the need to avoid high

levels of non-occupational noise exposure during the 14-hour period immediately preceding the audiometric examination.

(6) *Annual audiogram.* At least annually after obtaining the baseline audiogram, the employer shall obtain a new audiogram for each employee exposed at or above an 8-hour time-weighted average of 85 decibels.

(7) *Evaluation of audiogram.* (i) Each employee's annual audiogram shall be compared to that employee's baseline audiogram to determine if the audiogram is valid and if a standard threshold shift as defined in paragraph (g)(10) of this section has occurred. This comparison may be done by a technician.

(ii) If the annual audiogram shows that an employee has suffered a standard threshold shift, the employer may obtain a retest within 30 days and consider the results of the retest as the annual audiogram.

(iii) The audiologist, otolaryngologist, or physician shall review problem audiograms and shall determine whether there is a need for further evaluation. The employer shall provide to the person performing this evaluation the following information:

(A) A copy of the requirements for hearing conservation as set forth in paragraphs (c) through (n) of this section;

(B) The baseline audiogram and most recent audiogram of the employee to be evaluated;

(C) Measurements of background sound pressure levels in the audiometric test room as required in Appendix D: Audiometric Test Rooms.

(D) Records of audiometer calibrations required by paragraph (h)(5) of this section.

(8) *Follow-up procedures.* (i) If a comparison of the annual audiogram to the baseline audiogram indicates a standard threshold shift as defined in paragraph (g)(10) of this section has occurred, the employee shall be informed of this fact in writing, within 21 days of the determination.

(ii) Unless a physician determines that the standard threshold shift is not work related or aggravated by occupational noise exposure, the employer shall ensure that the following steps are taken when a standard threshold shift occurs:

(A) Employees not using hearing protectors shall be fitted with hearing protectors, trained in their use and care, and required to use them.

(B) Employees already using hearing protectors shall be refitted and retained in the use of hearing protectors and provided with hearing protectors offering greater attenuation if necessary.

(C) The employee shall be referred for a clinical audiological evaluation or an otological examination, as appropriate, if additional testing is necessary or if the employer suspects that a medical pathology of the ear is caused or aggravated by the wearing of hearing protectors.

(D) The employee is informed of the need for an otological examination if a medical pathology of the ear that is unrelated to the use of hearing protectors is suspected.

(iii) If subsequent audiometric testing of an employee whose exposure to noise is less than an 8-hour TWA of 80 decibels indicates that a standard threshold shift is not persistent, the employer:

(A) Shall inform the employee of the new audiometric interpretation; and

(B) May discontinue the required use of hearing protectors for that employee.

(9) *Revised baseline.* An annual audiogram may be substituted for the baseline audiogram when, in the judgment of the audiologist, otolaryngologist or physician who is evaluating the audiogram:

(i) The standard threshold shift revealed by the audiogram is persistent or

(ii) The hearing threshold shown in the annual audiogram indicates significant improvement over the baseline audiogram.

(10) *Standard threshold shift.* (1) As used in this section, a standard threshold shift is a change in hearing threshold relative to the baseline audiogram of an average of 10 dB or more at 2000, 3000, and 4000 Hz in either ear.

(ii) In determining whether a standard threshold shift has occurred, allowance may be made for the contribution of aging (presbycusis) to the change in hearing level by correcting the annual audiogram according to the procedure described in Appendix F: Calculation and Application of Age Correction to Audiograms.

(h) *Audiometric test requirements.* (1) Audiometric tests shall be pure tone, air conduction, hearing threshold examinations, with test frequencies including as a minimum 500, 1000, 2000, 3000, 4000, and 6000 Hz. Tests at each frequency shall be taken separately for each ear.

(2) Audiometric tests shall be conducted with audiometers (including microprocessor audiometers) that meet the specifications of, and are maintained and used in accordance with, American National Standard Specification for Audiometers, S3.6-1982.

(3) Pulsed-tone and self-recording audiometers. If used, shall meet the requirements specified in Appendix C: *Audiometric Measuring Instruments*.

(4) Audiometric examinations shall be administered in a room meeting the requirements listed in Appendix D: *Audiometric Test Rooms*.

(5) Audiometer calibration. (i) The functional operation of the audiometer shall be checked before each day's use by testing a person with known, stable hearing thresholds, and by listening to the audiometer's output to make sure that the output is free from distorted or unwanted sounds. Deviations of 10 decibels or greater require an acoustic calibration.

(ii) Audiometer calibration shall be checked acoustically at least annually in accordance with Appendix E: *Acoustic Calibration of Audiometers*. Test frequencies below 500 Hz and above 8000 Hz may be omitted from this check. Deviations of 15 decibels or greater require an exhaustive calibration.

(iii) An exhaustive calibration shall be performed at least every two years in accordance with sections 4.1.2, 4.1.3, 4.1.4.3, 4.2, 4.4.1, 4.4.2, 4.4.3, and 4.5 of the American National Standard Specification for Audiometers, S3.6-1980. Test frequencies below 500 Hz and above 8000 Hz may be omitted from this calibration.

(i) Hearing protectors. (1) Employers shall make hearing protectors available to all employees exposed to an 8-hour time-weighted average of 85 decibels or greater at no cost to the employees. Hearing protectors shall be replaced as necessary.

(2) Employers shall ensure that hearing protectors are worn:

(i) By any employee who is required by paragraph (b)(1) of this section to wear personal protective equipment; and

(ii) By any employee who is exposed to an 8-hour time-weighted average of 85 decibels or greater, and who:

(A) Has not yet had a baseline audiogram established pursuant to paragraph (g)(5)(ii); or

(B) Has experienced a standard threshold shift.

(3) Employees shall be given the opportunity to select their hearing protectors from a variety of suitable hearing protectors provided by the employer.

(4) The employer shall provide training in the use and care of all hearing protectors provided to employees.

(5) The employer shall ensure proper initial fitting and supervise the correct

use of all hearing protector.

(i) Hearing protector attenuation. (1) The employer shall evaluate hearing protector attenuation for the specific noise environments in which the protector will be used. The employer shall use one of the evaluation methods described in Appendix B: *Methods for Estimating the Adequacy of Hearing Protection Attenuation*.

(2) Hearing protectors must attenuate employee exposure at least to an 8-hour time-weighted average of 90 decibels as required by paragraph (b) of this section.

(3) For employees who have experienced a standard threshold shift, hearing protectors must attenuate employee exposure to an 8-hour time-weighted average of 85 decibels or below.

(4) The adequacy of hearing protector attenuation shall be re-evaluated whenever employee noise exposures increase to the extent that the hearing protectors provided may no longer provide adequate attenuation. The employee shall provide more effective hearing protectors where necessary.

(k) Training program. (1) The employer shall institute a training program for all employees who are exposed to noise at or above an 8-hour time-weighted average of 85 decibels, and shall ensure employee participation in such program.

(2) The training program shall be repeated annually for each employee included in the hearing conservation program. Information provided in the training program shall be updated to be consistent with changes in protective equipment and work processes.

(3) The employer shall ensure that each employee is informed of the following:

(i) The effects of noise on hearing;

(ii) The purpose of hearing protectors, the advantages, disadvantages, and attenuation of various types, and instructions on selection, fitting, use, and care; and

(iii) The purpose of audiometric testing, and an explanation of the test procedures.

(l) Access to information and training materials. (1) The employer shall make available to affected employees or their representatives copies of this standard and shall also post a copy in the workplace.

(2) The employer shall provide to affected employees any informational materials pertaining to the standard that are supplied to the employer by the Assistant Secretary.

(3) The employer shall provide, upon request, all materials related to the employer's training and education program pertaining to this standard to the Assistant Secretary and the Director.

(m) Recordkeeping —(1) Exposure measurements. The employer shall maintain an accurate record of all employee exposure measurements required by paragraph (d) of this section.

(2) Audiometric tests. (i) The employer shall retain all employee audiometric test records obtained pursuant to paragraph (g) of this section:

(ii) This record shall include:

(A) Name and job classification of the employee;

(B) Date of the audiogram;

(C) The examiner's name;

(D) Date of the last acoustic or exhaustive calibration of the audiometer; and

(E) Employee's most recent noise exposure assessment.

(F) The employer shall maintain accurate records of the measurements of the background sound pressure levels in audiometric test rooms.

(3) Record retention. The employer shall retain records required in this paragraph (m) for at least the following periods.

(i) Noise exposure measurement records shall be retained for two years.

(ii) Audiometric test records shall be retained for the duration of the affected employee's employment.

(4) Access to records. All records required by this section shall be provided upon request to employees, former employees, representatives designated by the individual employee, and the Assistant Secretary. The provisions of 29 CFR 1910.20 (a)-(e) and (g)-(i) apply to access to records under this section.

(5) Transfer of records. If the employer ceases to do business, the employer shall transfer to the successor employer all records required to be maintained by this section, and the successor employer shall retain them for the remainder of the period prescribed in paragraph (m) (3) of this section.

(n) Appendices. (1) Appendices A, B, C, D, and E to this section are incorporated as part of this section and the contents of these Appendices are mandatory.

(2) Appendices F and G to this section are informational and are not intended to create any additional obligations not

ATTACHMENT B

**Statement from the
Consensus Development Conference
on Early Identification of Hearing Impairment
in Infants and Young Children**

**Sponsored by the National Institute
on Deafness and Other Communicative Disorders
National Institutes of Health**



Consensus Development Conferences

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FOR RELEASE
Wednesday, March 3, 1993

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NIE PANEL RECOMMENDS HEARING SCREENING FOR ALL NEWBORNS

All infants should be screened for hearing impairment, according to a consensus development panel convened by the National Institutes of Health.

While the best opportunity to screen infants for signs of hearing impairment is before they are discharged from newborn nurseries, the panel urged that universal screening should be done no later than the first three months of life.

In the United States nearly 1 of every 1,000 children is born deaf. Many more are born with less severe hearing impairment while others develop impaired hearing during childhood. The first three years of life are the crucial period for developing speech and language skills. Reduced hearing acuity during this period can interfere with speech and language development, adversely affecting social and emotional growth.

While there are several methods available to identify hearing impairment during the first year of life, the average age of identifying hearing impaired American children is close to three years.

"There is a clear need in this country for improved methods and models for identifying hearing impairment in infants and young children," said panel chairman Dr. Gregory Matz, professor and chairman of the otolaryngology department at Loyola University in Chicago.

Currently, the only infants screened are those identified with one or more high risk factors associated with hearing impairment, including low birth weight or a family history of hearing impairment. However, these criteria fail to identify 50 to 70 percent of children born with hearing impairment.

The panel noted that recent technology advances have led to improved screening methods that can identify the majority of children with impaired hearing and recommended the use of two tests for universal screening.

Currently, the panel said, newborns should be screened before leaving the hospital with a test that measures otoacoustic emissions (OAE), which are low-level inaudible sounds produced by the inner ear. Infants who fail OAE testing should be screened with auditory brainstem response (ABR) audiometry, which measures function of the inner ear hearing nerve and parts of the brain involved in hearing.

While ABR testing has been the screening method of choice for high risk infants for nearly 15 years, its cost, testing time required, and technical difficulties have discouraged its use for screening large populations of infants. The recent development of OAE testing, which is fast, inexpensive, and noninvasive, prompted the panel to recommend, for the first time, universal screening of all newborns.

Newborn screening, the panel stated, is not a replacement for early childhood hearing tests, emphasizing the importance of continued universal surveillance of preschool children. The panel also encouraged greater public awareness and education of health care providers about the early signs of hearing impairment in infants and young children.

These recommendations were reported at the conclusion of the NIH Consensus Development Conference on Early Identification of Hearing Impairment in Infants and Young Children. This 3-day conference was sponsored by the National Institute on Deafness and Other Communication Disorders and NIH Office of Medical Applications of Research.

* * *

TELEVISION EDITORS: B-roll footage of different test methods is available by contacting Jo Bagley at 301-496-7243. Total run time is about 5 minutes.

RADIO EDITORS: A brief audio report on this conference with actualities will be available for taping March 8-12, 1993, by calling the NIH Radio News Service at 1-800-MED-DIAL.

ATTACHMENT C

**Joint Committee on Infant Hearing
1990 Position Statement**

**American Academy of Pediatrics
American Academy of Otolaryngology
American Speech-Language-Hearing Association**

**Joint Committee on
Infant Hearing
1990 Position
Statement**

The following expanded position statement was developed by the Joint Committee on Infant Hearing and approved by the American Speech-Language-Hearing Association (ASHA) Legislative Council (LC 40-90) in November 1990. Joint Committee member organizations that approved this position statement and their respective representatives who prepared this statement include the following: American Speech-Language-Hearing Association—Fred H. Bess, chair; Noel D. Matkin, and Evelyn Cherow, ex officio; American Academy of Otolaryngology—Head and Neck Surgery—Kenneth M. Grunstein, co-chair; American Academy of Pediatrics—Allen Ehrendorfer and William P. Powers; Council of Representatives of the Deaf (ACRD)—Bell Associates for the Deaf; American College of Educators of the Hearing Impaired; Commission of American Instructors of the Deaf; and the Conference of Educational Administrators Serving the Deaf—Lits Aldridge and Barbara Bodner Johnson; Directors of Speech and Hearing Programs in State Health and Welfare Agencies—Thomas Mahoney, Consultants: Alan Salamy and Gregory J. Metz; Ann L. Carey, 1988–1990 vice president for professional and governmental affairs, was the ASHA monitoring vice president.

I. Background

The early detection of hearing impairment in children is essential in order to initiate the medical and educational intervention critical for developing optimal communication and social skills. In 1982, the Joint Committee on Infant Hearing recommended identifying infants at risk for hearing impairment by means of seven criteria and suggested follow-up audiological evaluation of these infants until accurate assessments of hearing could be made (ASHA, 1982). In recent years, advances in science and technology have increased the chances for survival of markedly premature and low birth weight neonates and other severely compromised newborns. Because moderate to severe sensorineural hearing loss can be confirmed in 2.5% to 5.0% of neonates manifesting any of the previously published risk criteria, auditory screening of at-risk newborns is warranted (Hostord-Dunn, Johnson, Simmons, Malachowski, & Low, 1987; Jacobson &

Morehouse, 1984; Mahoney & Eichwald, 1987; Stein, Ozdamer, Kraus, & Fason, 1983). Those infants who have one or more of the risk factors are considered to be at increased risk for sensorineural hearing loss.

Recent research and new legislation (P.L. 99-457) suggests the need for expansion and modification of the 1982 criteria. This 1990 statement revises the risk criteria and makes recommendations for the identification and management of hearing-impaired neonates and infants. The Joint Committee recognizes that the performance characteristics of these new risk factors are not presently known; further study and critical evaluation of the risk criteria are therefore encouraged. The protocols recommended by the Committee are considered optimal and are based on both clinical experience and current research findings. The Committee recognizes, however, that the recommended protocols may not be appropriate for all institutions and that modifications in screening approaches will be necessary to accommodate the specific needs of a given facility. Such factors as cost and availability of equipment, personnel and follow-up services are important considerations in the development of a screening program (Turner, 1990).

II. Identification

A. Risk Criteria: Neonates (birth - 25 days)

The risk factors that identify those neonates who are at-risk for sensorineural hearing impairment include the following:

1. Family history of congenital or delayed onset childhood sensorineural impairment.
2. Congenital infection known or suspected to be associated with sensorineural hearing impairment such as toxoplasmosis, syphilis, rubella, cytomegalovirus and herpes.
3. Craniofacial anomalies including morphologic abnormalities of the pinna and ear canal, absent pituitary, low hairline, etcetera.

Reference the material at bottom.

Joint Committee on Infant Hearing (1991). 1990 position statement. *ASHA*, 33 (Suppl. 5), 3-6.

4. Birth weight less than 1500 grams (~3.3 lbs.).
 5. Hyperbilirubinemia at a level exceeding indication for exchange transfusion.
 6. Otoxic medications including but not limited to the aminoglycosides used for more than 5 days (e.g., gentamicin, tobramycin, kanamycin, streptomycin) and loop diuretics used in combination with aminoglycosides.
 7. Bacterial meningitis.
 8. Severe depression at birth, which may include infants with Apgar scores of 0-3 at 5 minutes or those who fail to initiate spontaneous respiration by 10 minutes or those with hypotonia persisting to 2 hours of age.
 9. Prolonged mechanical ventilation for a duration equal to or greater than 10 days (e.g., persistent pulmonary hypertension).
 10. Stigmata or other findings associated with a syndrome known to include sensorineural hearing loss (e.g., Waardenburg or Usher's Syndrome).
- B. Risk Criteria: Infants (29 days - 2 years)
- The factors that identify those infants who are at-risk for sensorineural hearing impairment include the following:
1. Parent/caregiver concern regarding hearing, speech, language and/or developmental delay.
 2. Bacterial meningitis.
 3. Neonatal risk factors that may be associated with progressive sensorineural hearing loss (e.g., cytomegalovirus, prolonged mechanical ventilation and inherited disorders).
 4. Head trauma especially with either longitudinal or transverse fracture of the temporal bone.
 5. Stigmata or other findings associated with syndromes known to include sensorineural hearing loss (e.g., Waardenburg or Usher's Syndrome).
 6. Otoxic medications including but not limited to the aminoglycosides used for more than 5 days (e.g., gentamicin, tobramycin, kanamycin, streptomycin) and loop diuretics used in combination with aminoglycosides.
 7. Children with neurodegenerative disorders such as neurofibromatosis, myoclonic epilepsy, Werdnig-Hoffman disease, Tay-Sach's disease, infantile Gaucher's disease, Nieman-Pick disease, any metachromatic leukodystrophy, or any infantile demyelinating neuropathy.

8. Childhood infectious diseases known to be associated with sensorineural hearing loss (e.g., mumps, measles).

III. Audiologic Screening Recommendations for Neonates and Infants

A. Neonates

Neonates who manifest one or more items on the risk criteria should be screened, preferably under the supervision of an audiologist. Optimally, screening should be completed prior to discharge from the newborn nursery but no later than 3 months of age. The initial screening should include measurement of the auditory brainstem response (ABR) (ASHA, 1989). Behavioral testing of newborn infants' hearing has high false-positive and false-negative rates and is not universally recommended. Because some false-positive results can occur with ABR screening, ongoing assessment and observation of the infant's auditory behavior is recommended during the early stages of intervention. If the infant is discharged prior to screening, or if ABR screening under audiological supervision is not available, the child ideally should be referred for ABR testing by 3 months of age but never later than 6 months of age.

The acoustic stimulus for ABR screening should contain energy in the frequency region important for speech recognition. Clicks are the most commonly used signal for eliciting the ABR and contain energy in the speech frequency region (ASHA, 1989). Pass criterion for ABR screening is a response from each ear at intensity levels 40 dB nHL or less. Transducers designed to reduce the probability of ear-canal collapse are recommended.

If consistent electrophysiological responses are detected at appropriate sound levels, then the screening process will be considered complete except in those cases where there is a probability of progressive hearing loss (e.g., family history of delayed onset, degenerative disease, meningitis, intrauterine infections or infants who had chronic lung disease, pulmonary hypertension or who received medications in doses likely to be ototoxic). If the results of an initial screening of an infant manifesting any risk criteria are equivocal, then the infant should be referred for general medical, otological, and audiological follow-up.

B. Infants

Infants who exhibit one or more items on the risk criteria should be screened as soon as possible but no later than 3 months after the child has been identified as at-risk. For infants less than 6 months of age, ABR screening (see II.A) is recommended. For infants older than 6 months, behavioral testing using a conditioned response or ABR testing are appropriate approaches. Infants who fail the screen should be referred for a comprehensive audiological evaluation. This evaluation may include ABR, behavioral testing (> 6 months) and acoustic immittance measures (see ASHA, 1989 Guidelines, for recommended protocols by developmental age).

IV. Early Intervention for Hearing-Impaired Infants and Their Families

When hearing loss is identified, early intervention services should be provided, in accordance with Public Law 99-457. Early intervention services under P.L. 99-457 may commence before the completion of the evaluation and assessment if the following conditions are met: (a) parental consent is obtained, (b) an interim individualized family service plan (IFSP) is developed, and (c) the full initial evaluation process is completed within 45 days of referral.

The interim IFSP should include the following:

- The name of the case manager who will be responsible for both implementation of the interim IFSP and coordination with other agencies and persons;
- B. The early intervention services that have been determined to be needed immediately by the child and the child's family.

These immediate early intervention services should include the following:

- Evaluation by a physician with expertise in the management of early childhood otologic disorders.
- Evaluation by an audiologist with expertise in the assessment of young children, to determine the type, degree, and configuration of the hearing loss, and to recommend assistive communication devices appropriate to the child's needs (e.g., hearing aids, personal FM systems, vibratotactile aids).
- Evaluation by a speech-language pathologist, teacher of the hearing-impaired, audiologist, or other professional with expertise in the assessment of communication skills in hearing-impaired children, to develop a program of early intervention consistent with the needs of the child and preferences of the family. Such intervention would be cognizant of and sensitive to cultural values inherent in familial deafness.
- Family education, counseling and guidance, including home visits and parent support groups to provide families with information, child management skills and emotional support consistent with the needs of the child and family and their culture.
- Special instruction that includes:
 - the design and implementation of learning environments and activities that promote the child's development and communication skills;
 - curriculum planning that integrates and coordinates multidisciplinary personnel and resources so that intended outcomes of the IFSP are achieved; and,

- ongoing monitoring of the child's hearing status and amplification needs and development of auditory skills.

V. Future Considerations for Risk Criteria

Because of the dynamic changes occurring in neonatal-prenatal medicine, the committee recognizes that forthcoming research may result in the need for revision of the 1990 risk register. For example, the committee has concerns about the possible ototoxic effects on the fetus from maternal drug abuse; however, present data are insufficient to determine whether the fetus or neonate are at risk for hearing loss. In addition, yet-to-be-developed medications may have ototoxic effects on neonates and infants. Therefore, the committee advises clinicians to keep apprised of published reports demonstrating correlations between maternal drug abuse and ototoxicity and between future antimicrobial agents and ototoxicity. Clinicians should also take into account the possible interactive effects of multiple medications administered simultaneously. Finally, the committee recommends that the position statement be examined every 3 years for possible revision.

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ATTACHMENT D**Statement on Middle Ear Disease
and Language Development****American Academy of Pediatrics****STATEMENT ON MIDDLE EAR DISEASE AND LANGUAGE DEVELOPMENT
OF THE ACADEMY OF PEDIATRICS**Reproduced from News and Comments, Academy of Pediatrics, 1984

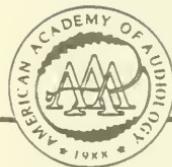
There is growing evidence demonstrating a correlation between middle ear disease with hearing impairment and delays in the development of speech, language and cognitive skills. A parent or other caretaker may be the first person to detect such early symptoms as irritability, decreased responsiveness and disturbed sleep. Middle ear disease may be so subtle that a full evaluation for this condition should combine pneumatic otoscopy, and possibly tympanometry, with a direct view of the tympanic membrane. This statement is not meant to be a recommendation for specific treatment methods. When a child has frequently recurring acute otitis media and/or middle ear effusion persisting for longer than three months, hearing should be assessed and the development of communicative skills must be monitored.

The Committee feels it is important that the physician inform the parent that a child with middle ear disease may not hear normally. Although the child may withdraw socially and diminish experimentation with verbal communication, the parent should be encouraged to continue communicating with the child when loudly and clearly speaking. Such measures, along with prompt restoration of hearing whenever possible, may help to diminish the likelihood that a child with middle ear disease will develop a communicative disorder. Middle ear disease can occur in the presence of a sensory neural hearing loss. Any child whose parent expresses concern about whether the child hears should be considered for referral for behavioral audiology without delay.

ATTACHMENT E

**Position Statement
Task Force on Hearing Impairment
in Aged People**

American Academy of Audiology



POSITION STATEMENT

**Task Force on Hearing Impairment
in Aged People**

Background

One of the demographic imperatives affecting the United States' present and future course is the aging of Americans. The number of persons aged 65 years and older is growing more rapidly than the rest of the U.S. population.¹⁰ The expansion of the nation's aged population has considerable implication for health status, health care utilization, and health care delivery.

Hearing impairment is the third most commonly reported chronic problem affecting the aged population.¹¹ At present, more than 7 million aged persons suffer from some degree of hearing impairment.⁴ Given the rapid growth in the population over 75 years of age, it is projected that more than 11 million members of this age group will have significant hearing impairments by the turn of the century. The aging of the population will be accompanied by an increase in the prevalence and severity of hearing loss, due to the direct correlation between age and hearing loss.

Presbycusis often is defined as hearing loss associated with the aging process. However, the Committee on Hearing, Bioacoustics and Biomechanics¹² considers presbycusis to be the sum of hearing losses which result from several varieties of physiological degeneration. These include insults due to noise exposure, ototoxic agents, psychopharmacology, and medical disorders as well as the effects of physiological aging.¹³ Irrespective of the etiology, the interference with communication created by sensorineural hearing impairment has a profound negative effect on the lives of aged persons. In addition to its threat to personal safety, hearing impairment has an adverse effect on physical, cognitive, emotional, social, and behavioral function.^{14,15} These manifestations are often viewed by the hearing impaired person as representing a very significant handicap, despite the audiologic appearance of a relatively mild hearing loss.¹³ Fortunately, the negative influences of hearing impairment are amenable to intervention.¹⁵ Hence, hearing health care professionals must strive to identify individuals with hearing impairments in order to remediate the permanent impact of hearing loss.

Identification of Impairment in the Aged Population

The U.S. Preventive Services Task Force¹⁶ has recommended that aged persons be screened for hearing impairment. The goal of any screening program is to reach as large a proportion of the eligible target population as possible. To this end, a number of potential settings are available for screening aged individuals for hearing impairments and handicaps. Potential settings for screening include health fair, community based programs, primary care physician's offices, acute care settings, nursing facilities and possibly the home. Each of these settings has advantages and disadvantages, with the limiting factors in any screening setting being ambient noise level, professional resources available to administer the screen, and money available to purchase the requisite equipment. Nevertheless, a screening program should use tools that are appropriate for the particular setting, and should employ professionals who are well trained to perform the screen. Screening conducted in the offices of primary care physicians is particularly attractive because most persons over 65 years old visit their primary care physician on an annual basis and the office may provide a relatively quiet setting for screening.

A number of screening tools are available to detect clinically important hearing impairments and handicaps in aged people. An impairment is defined as "any loss or abnormality of psychological, physiological or anatomical structure or function," whereas a handicap is "a disadvantage for a given individual resulting from an impairment that limits



or prevents the fulfillment of a role that is normal for that individual.²⁴ Screening tools designed to detect hearing handicaps and impairments fall into two broad categories: hearing handicap scales and audiometric screening. Hearing handicap scales assess the perceived effects of hearing loss on various aspects of daily function. A screening version of one such scale, the Hearing Handicap Inventory for the Elderly (HHIE-S), is a reliable and valid method for identifying handicapping hearing impairment among aged persons.^{12,15,23} The sensitivity and specificity rates of this tool are approximately 70 to 80% for identifying hearing losses of moderate or greater degree.

An audiometric screen is a quick and valid method for detecting hearing impairment among aged individuals. Screening for hearing impairment requires the use of one of two methods: 1) a calibrated audiometer in a quiet environment, or 2) an otoscope with a built-in audiometer (e.g., audioscope). The advantage of using a calibrated audiometer is that it is a valid and reliable technique. The requirement of a quiet environment, however, may not be practical in all settings. The audioscope delivers selected frequencies (500, 1000, 2000, and 4000 Hz) at one of three intensities to the entrance of the ear canal. The audioscope has an overall accuracy for hearing screening of 75-80%.^{2,5,13} Screening with both a hearing handicap scale and either an audiometer or audioscope is recommended,²² because the correlation between hearing impairment and handicap is imperfect.¹⁸ Thus, combining the two techniques may increase the overall accuracy of the screening program.¹²

Once identified through a screening program as being likely to have a hearing impairment or handicap, an aged person should be referred to an audiologist for thorough audiological evaluation and appropriate recommendations for aural rehabilitation. Medical clearance should also be obtained to rule out pathological conditions that would contraindicate hearing aid use. Unfortunately, the rate of compliance with the recommendation for further audiological evaluation among aged persons can be as low as 50% and ranges between 50 and 90%.^{10,11,19} Moreover, in most circumstances, only 10 to 20% of this population subsequently obtains hearing aids. Barriers to compliance include confusion about the hearing aid delivery system, the cost of evaluation and hearing aids, social stigma, unwanted amplification of background noise, and myths about the efficacy of hearing aids.²⁵ An integral part of any screening program should be mechanisms to enhance the probability that individuals will comply with referrals for additional evaluation and remediation.

Strategies for Intervention

The audiological evaluation establishes the need for possible aural rehabilitation and medical evaluation. In most cases, the aged person's auditory capabilities can be

assessed with standard audiological techniques.

Occasionally, the behavioral assessment must be modified to accommodate physical or cognitive limitations of aged individuals. The typical presbycusis hearing loss is sensorineural, sloping, and ranges in degree from mild to moderately-severe.^{7,14} Moreover, pure tone sensitivity tends to deteriorate with age, and males exhibit poorer thresholds than females of comparable age.^{7,14} The hearing loss observed in older people often limits their reception of conversational speech, especially in noisy environments.⁴ While the typical presbycusis hearing loss is not amenable to medical intervention, the handicapping effects of the hearing impairment often can be remedied successfully with selected audiological intervention strategies.

Hearing aids are the principal resource for improving communication and reducing handicaps in aged people. Hearing aids amplify speech so that it becomes comfortably audible to the hearing-impaired user, but does not exceed the user's tolerance level for loud sounds. Significant improvements in hearing aid design have enabled greater flexibility in selecting hearing aids for the typical hearing loss patterns associated with aging. The newest generation of hearing aids includes digitally controlled analog designs. In addition, hearing aids can now be modified to ease manipulation of volume controls, battery compartments, and switches, thereby improving hearing aid use for aged individuals with manual dexterity problems. Recent evidence indicates that hearing aids successfully reduce the social, emotional, and functional handicap often resulting from hearing impairment in aged people.¹³

In addition to hearing aids, assistive living devices can be used effectively by aged people to improve communication in specific situations. Assistive listening devices transmit acoustic signals by wire, magnetic induction, infrared light or radio frequency. They are particularly useful when room acoustics are poor. The use of assistive devices is expanding in theaters, public meeting rooms, and houses of worship. They can be adapted for use in personal living areas and common areas of nursing homes where communication may be difficult.

Alerting devices, which use lights to signal fire alarms or the telephone or doorbell ringing, can reduce the hazards to safety imposed by the hearing loss. Telephone amplifiers with adjustable volume controls are becoming an integral part of many new telephone designs. The television caption decoder can be used by those with reasonable vision, but whose hearing is limited despite rehabilitation. Assistive listening and alerting devices are effective, and their use should be encouraged in hospitals, nursing facilities, and the home.

Hearing aids should be offered within the greater context of aural rehabilitation. Aural rehabilitation includes any non-medical intervention designed to remediate hearing loss and improve communication. It also includes counseling the hearing-impaired person and his or her family about the

implications of hearing impairment, as well as conducting a hearing aid orientation and follow-up to ensure proper hearing aid use. Suggestions for maximizing the use of visual cues and residual hearing are provided. Formal speechreading instruction or auditory training may be recommended to enhance the information received through amplification.

The aural rehabilitation process should include not only the aged hearing-impaired person, but a family member or significant other as well. For the aged individual to achieve maximum benefit, the family and health care staff must appreciate the impact of the hearing impairment, the operation of the amplification device, the benefits and limitations of the procedures being used, and their own role in improving and promoting communication.

Role of the Audiologist

The audiologist is the primary hearing health care provider for aged individuals with hearing impairment. An audiologist is a person who, by virtue of academic and clinical training, and appropriate certification and/or licensure, is uniquely qualified to provide a comprehensive array of professional services relating to the prevention, evaluation, and rehabilitation of auditory impairment and its associated communicative disorders. The audiologist may provide these services independently or as part of an interdisciplinary professional team involved in identification, diagnosis, and treatment of individuals who have disorders related to auditory dysfunction.

The audiologist serves as the primary expert in the assessment and non-medical diagnosis of auditory impairment in aged people. Assessment includes, but is not limited to, the administration and interpretation of behavioral, electroacoustic, and electrophysiologic measures of the status of peripheral and central auditory systems and measures of hearing handicap. Methods of assessment include hearing-handicap scales, pure-tone audiometry, immittance audiometry, speech audiometry, and auditory evoked potential measurement.

Audiologists are uniquely qualified to provide a full range of auditory rehabilitative services to aged individuals. The audiologist is the primary individual responsible for the evaluation and fitting of all types of amplification systems, including hearing aids and assistive listening devices. The audiologist determines whether the aged individual is a suitable candidate for an amplification system, evaluates the benefit that the individual may expect to derive from such systems, and makes an appropriate recommendation. In connection with such recommendations, the audiologist may take ear impressions, fit and dispense the amplification system, and provide counseling regarding its use.

The audiologist also provides rehabilitative services and education to individuals with auditory impairment, to family members, and to the public. The audiologist provides

information concerning hearing and hearing impairment, the use of prosthetic devices, and strategies for improving speech recognition by exploring auditory, visual, and tactile speech information. The audiologist also counsels patients regarding the effects of auditory impairment on communicative and psychosocial status. In addition, the audiologist determines the need for additional aural rehabilitation and, if indicated, the nature of the rehabilitation program. In connection with such determinations, the audiologist may conduct individual and/or group rehabilitation programs.

The audiologist serves as an advocate for aged individuals by encouraging equal access for those with communicative disorders, by prompting "self-help" consumer groups, and by encouraging third-party reimbursement of audiological services. The audiologist should be an integral member of any multidisciplinary team involved in the evaluation of the social, psychological, physical, and mental status of elderly people. The audiologist also serves aged people by promoting awareness of hearing impairment, available audiological services, and available remediation devices and programs to the hearing-impaired individuals, their spouses and children, and to other caretakers who constitute their support system.

Recommendations

The membership of the American Academy of Audiology seeks to maximize communication skills in aged hearing-impaired individuals. A comprehensive approach for providing effective services to aged individuals involves cooperative efforts among a variety of professional organizations and specialists. As a consequence, the Academy membership actively pursues close professional ties with other gerontology specialists toward meeting the hearing health care needs of aged people.

The American Academy of Audiology has developed five recommendations for improving the quality of life for hearing-impaired aged individuals.

1. The Academy advocates the use of screening procedures for identifying persons with hearing impairment or hearing handicap. Screening procedures should be used to identify the greatest number of hearing-impaired aged people. Screening should be coupled with efforts to maximize compliance with referral recommendations for audiological or medical evaluation.
2. The Academy promotes the provision of high quality audiological services for aged people. State-of-the-art knowledge and technology should be applied in the evaluation of hearing impairment in aged individuals as well as in the selection of aural rehabilitative procedures, including hearing aids, for aged individuals.
3. The Academy promotes funding for research on hearing impairment and aging by government agencies and private foundations. Critical issues that need investigation include prevention of age-related hearing loss; understanding the

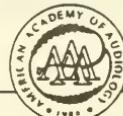
- auditory degenerative processes that account for age-related hearing loss; improving the design of hearing aids to overcome specific speech understanding problems of aged people; and developing valid outcome measures of audiological management strategies.
- 4 The Academy promotes equitable third-party payment from insurance companies, retirement health plans, state agencies, and federal agencies for hearing-related services and devices for aged people. The limited financial resources of many older people often restrict access to effective audiological services and therefore prevent them from receiving the benefits of a hearing aid.
- 5 The Academy promotes public education about hearing impairment in aged Americans. Practical information and suggestions should be provided to the group, including warning signs of hearing loss, where to go for help, and the benefits of amplification. Common misconceptions about hearing impairment and hearing aids also need to be dispelled. The Academy was founded in 1988 to "improve service to the hearing impaired by advancing the highest professional standards for diagnosis, habilitation, rehabilitation, and research in hearing and its disorders." These guiding principles apply specifically, and most importantly, to aged individuals, because they comprise more than half of the hearing-impaired population in the United States and their numbers are increasing dramatically. The American Academy of Audiology is committed to fostering excellence in hearing health care for senior citizens.

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This report was prepared by the following Academy Task Force Members: Sandra Gordon-Salant, (Chair), Frank Bialostozky, Michael Lichtenstein, Brad Stach, and Barbara Weinstein. Published in *Audiology Today*, Volume 3, No. 6, November/December, 1991.



ATTACHMENT F

Scope of Practice Document

American Academy of Audiology

CLINIC PRACTICE

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Scope of Practice

Scope of Practice

I. Purpose

The purpose of this document is to define the profession of audiology by its scope of practice. This document outlines those activities that are within the specialty of the profession. This Scope of Practice statement is intended to be used by audiologists, allied professionals, consumers of audiological services, and the general public. It serves as a reference for issues of service delivery, third-party reimbursement, legislation, consumer education, regulatory action, state and professional licensure and inter-professional relations. The document is not intended to be an exhaustive list of activities in which audiologists engage. Rather, it is a broad statement of professional practice. Periodic updating of any scope of practice statement is necessary as technologies and perspectives change.

II. Definition of an Audiologist

The central theme of the profession of audiology is auditory impairment and its associated communicative disorders. Audiologists are primarily concerned with the identification, evaluation, and rehabilitation of the individual with either peripheral or central auditory impairment, and with the prevention of such impairment. All professional activities related to this central theme fall within the purview of audiology. In addition, professional activities related to vestibular function fall within the competence of audiologists. An audiologist is a person who, by virtue of academic and clinical training and appropriate certification and/or licensure, is uniquely qualified to provide a comprehensive array of professional services related to the assessment and rehabilitation of persons with auditory and vestibular impairments, and to the prevention of these impairments. The audiologist serves in a number of roles: clinician, therapist, teacher, consultant, researcher and administrator.

Audiologists provide clinical and academic training to students in audiology. Audiologists teach physicians and medical students about non-medical and medical aspects of hearing and hearing loss. They also provide information and training on all aspects of hearing and vestibular function and communication disorders and rehabilitation to other professionals including psychology, counseling, rehabilitation, education and other related professions. Audiologists also provide information and services to business and industry. Further, audiologists serve as expert witnesses within the boundaries of forensic audiology.

The audiologist is an independent practitioner, who provides services in hospitals, clinics, schools, private practices and other settings in which audiological services are relevant.

III. Scope of Practice

The scope of practice of audiologists is defined by the training and knowledge base of professionals who are licensed and certified to practice as audiologists. Areas of competence include assessment and rehabilitation of individuals with auditory and vestibular disorders, prevention of hearing loss, and research in

Development of a Scope of Practice document began in 1990 with the work of the ad hoc Scope of Practice, chaired by Alison Grimes. The document was discussed and debated by the governing bodies of the Academy for nearly two years. It was put aside for a time because of other pressing issues facing the Academy. Following discussion and revision, the Scope of Practice document published here was adopted by the Executive Committee and Board of Representatives during their meeting on October 23, 1992. Previously, a Scope of Practice document for audiologists was published by ASA in conjunction with Speech-Language Pathologists (Scope of Practice, Speech-Language-Pathology and Audiology, ASA, 32, suppl. 2, 1990).

The Scope of Practice document describes the range of interests, capabilities and professional activities of audiologists. It defines audiologists as independent practitioners and provides examples of settings in which they are engaged. It is not intended to exclude participation in activities outside of those delineated in the document. The overriding principle is that members of the Academy will provide only those services for which they are adequately prepared through their academic and clinical training and their experiences, and that their practice is consistent with the Academy Code of Ethics.

As a dynamic and growing profession, the field of audiology will change over time as new information is acquired. The Scope of Practice document will receive regular review for consistency with current knowledge and practice. The Executive Committee welcomes member input on this document.

CLINIC PRACTICE

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normal and disordered auditory and vestibular function. The practice of audiology includes:

A. Assessment

Specifically, assessment of hearing includes the administration and interpretation of behavioral, electroacoustic, and electrophysiologic measures of the peripheral and central auditory systems. Assessment of the vestibular system includes administration and interpretation of clinical and electrophysiologic tests of equilibrium. Assessment is accomplished using standardized testing procedures and appropriately calibrated instrumentation.

B. Rehabilitation

The audiologist is the professional who provides the full range of rehabilitative services for persons with hearing impairment. The audiologist is responsible for the evaluation and fitting of all types of amplification devices, including hearing aids and assistive listening devices. The audiologist determines the appropriateness of amplification systems for persons with hearing impairment, evaluates their benefit, and provides counseling regarding their use. Audiologists conduct otoscopic examinations, clean ear canals, take ear impressions, fit and dispense hearing aids and other amplification systems.

Audiologists are also involved in the rehabilitation of persons with vestibular disorders. They may participate as full members of vestibular rehabilitation teams to recommend and carry out goals of vestibular rehabilitation therapy including, for example, habituation exercises, balance retraining exercises, and general conditioning exercises.

The audiologist is the member of the cochlear implant team who determines candidacy based on auditory and communication information. The audiologist provides pre- and post-surgical assessment, counseling, auditory training, rehabilitation, implant programming, and maintenance of implant hardware.

The audiologist provides rehabilitation to persons with hearing impairment, and is a source of information for family members, other professionals and the general public. Counseling regarding hearing loss, the use of hearing prosthetic devices and strategies for improving speech recognition is within the expertise of the audiologist. Additionally, the audiologist provides counseling regarding the effects of hearing loss on communication and psychosocial status in personal, social and vocational arenas.

The audiologist administers services to students of all ages with hearing impairment from pre-school through high school, including identification, evaluation and rehabilitation. The audiologist is an integral part of the team within the school system which manages hearing impaired students and students with central auditory processing

disorders. The audiologist serves as the resource for school personnel in the development of Individualized Educational Programs (IEP's) and in matters pertaining to classroom acoustics, assistive listening systems, hearing aids and communication, and maintains both classroom assistive systems as well as student's personal hearing aids. The audiologist administers hearing screening programs in schools, and trains and supervises non-audiologists performing hearing screening in the educational setting.

C. Hearing Conservation

The audiologist designs, implements and coordinates industrial and community hearing conservation programs. This includes identification and amelioration of noise-hazardous conditions, identification of hearing loss, recommendation and counseling for use of hearing protection, employee education, and the training and supervision of non-audiologists performing hearing screening in the industrial setting.

D. Research

The audiologist is one of the professionals responsible for the design, implementation, analysis, interpretation, and administration of research related to the auditory and vestibular systems.

E. Additional Expertise

Some audiologists, by virtue of education, experience and personal choice, choose to specialize in a particular specialty area of practice and thereby confine their skills, knowledge and practice to that specialty. Further, some audiologists, by virtue of education, experience and personal choice, engage in activities outside of those defined in this scope of practice. Nothing in this document shall be construed to limit individual freedom of choice in this regard provided that the activity is consistent with the American Academy of Audiology Code of Ethics.

This document will be reviewed, revised and updated periodically in order to reflect changing clinical demands of audiologists and in order to keep pace with the changing scope of practice reflected by these changes and innovations in this specialty.

ATTACHMENT G

Code of Ethics Document

American Academy of Audiology

A C A D E M Y · A F F A I R S

G-1

Code of Ethics



Part I Statement of Principles and Rules

Principle 1: Members shall provide professional services with honesty and compassion and shall respect the dignity, worth, and rights of those served.

Rule 1a: Individuals shall not limit the delivery of professional services on any basis that is unjustifiable, or irrelevant to the need for the potential benefit from such services.

Principle 2: Members shall maintain high standards of professional competence in rendering services, providing only those professional services for which they are qualified by education and experience.

Rule 2a: Individuals shall use available resources, including referrals to other specialists, and shall not accept benefits or items of personal value for receiving or making referrals.

Rule 2b: Individuals shall exercise all reasonable precautions to avoid injury to persons in the delivery of professional services.

Preamble

The Code of Ethics of the American Academy of Audiology contains rules and standards that allow for the proper delivery of audiological services, contributions to the advancement of audiology, and the integrity of the profession. The Code of Ethics consists of ten parts. Part I is the Statement of Principles and Rules, part II is membership, part III is members of the Academy, part IV is public relations, and part V is the Procedures, bylaws, and processes which enable enforcement of the Principles and Rules.

Rule 2c: Individuals shall not provide services except in a professional relationship, and shall not discriminate in the provision of services to individuals on the basis of sex, race, religion, national origin, sexual orientation, or general health.

Rule 2d: Individuals shall provide appropriate supervision and assume full responsibility for services delegated to supportive personnel. Individuals shall not delegate any service requiring professional competence to persons unqualified.

Rule 2e: Individuals shall not permit personnel to engage in any practice that is a violation of the Code of Ethics.

Rule 2f: Individuals shall maintain professional competence, including participation in continuing education.

Principle 3: Members shall maintain the confidentiality of the information and records of those receiving services.

Rule 3a: Individuals shall not reveal to unauthorized persons any professional or personal information obtained from the person served professionally, unless required by law.

A C A D E M Y A F F A I R S

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Principle 4: Members shall provide only services and products that are in the best interest of those served.

Rule 4a: Individuals shall not exploit persons in the delivery of professional services.

Rule 4b: Individuals shall charge only for services rendered.

Rule 4c: Individuals shall not participate in activities that constitute a conflict of professional interest.

Rule 4d: Individuals shall not accept compensation for supervision or sponsorship beyond reimbursement of expenses.

Principle 5: Members shall provide accurate information about the nature and management of communicative disorders and about the services and products offered.

Rule 5a: Individuals shall provide persons served with the information a reasonable person would want to know about the nature and possible effects of services rendered, or products provided.

Rule 5b: Individuals may make a statement of prognosis, but shall not guarantee results, mislead, or misinform persons served.

Rule 5c: Individuals shall not carry out teaching, or research activities in a manner that constitutes an invasion of privacy, or that fails to inform persons fully about the nature and possible effects of these activities, affording all persons informed free-choice and participation.

Rule 5d: Individuals shall maintain documentation of professional services rendered.

Principle 6: Members shall comply with the ethical standards of the Academy with regard to public statements.

Rule 6a: Individuals shall not misrepresent their educational degrees, training, credentials, or competence. Only degrees earned from regionally accredited institutions in which training was obtained in audiology, or a directly related discipline, may be used in public statements concerning professional services.

Rule 6b: Individuals' public statements about professional services and products shall not contain representations or claims that are false, misleading, or deceptive.

Principle 7: Members shall honor their responsibilities to the public and to professional colleagues.

Rule 7a: Individuals shall not use professional or commercial affiliations in any way that would mislead or limit services to persons served professionally.

Rule 7b: Individuals shall inform colleagues and the public in a manner consistent with the highest professional standards about products and services they have developed.

Principle 8: Members shall uphold the dignity of the profession and freely accept the Academy's self-imposed standards.

Rule 8a: Individuals shall not violate these Principles and Rules, nor attempt to circumvent them.

Rule 8b: Individuals shall not engage in dishonesty or illegal conduct that adversely reflects on the legal conduct that adversely reflects on the profession.

Rule 8c: Individuals shall inform the Ethical Practice Board when there are reasons to believe that a member of the Academy may have violated the Code of Ethics.

Rule 8d: Individuals shall cooperate with the Ethical Practice Board in any matter related to the Code of Ethics.

ATTACHMENT H

Position Paper

**The American Academy of Audiology
and the Professional Doctorate (Au.D.)****American Academy of Audiology****POSITION STATEMENT****The American Academy of Audiology and the
Professional Doctorate (Au.D.)****Introduction**

The issue of the professional doctorate (Au.D.) as the appropriate entry-level degree for audiology has been growing in importance and interest. At the 1991 Convention of the Academy, the Executive Committee appointed an ad hoc committee from the Board of Representatives consisting of Charles Berlin, James Curran, Patricia Nordstrom and Gretchen Syler, to produce a document utilizing sections of two previously unpublished working papers, as well as other sources. James Curran and Wayne Olsen were asked to further refine the position paper in terms of style and expression without change to its content. The Board of Representatives and Executive Committee unanimously passed the final revised document. It clearly states the Academy and its membership believe in the critical need for improvement in the quality of education that future audiologist-practitioners will receive.

Policy Statements

The specific purpose of the professional doctorate in audiology is to prepare highly skilled practitioners. Professional doctorate programs in audiology must significantly exceed the academic and training experiences provided by Master's level programs and provide at least four years training and education after the completion of accredited baccalaureate work.³ Such programs must demonstrate sufficient depth and breadth to warrant the doctoral designation.⁴ An entirely different degree designation, the Au.D. (Doctor of Audiology), is necessary to describe this professional degree and to differentiate it from the research-oriented Ph.D.

The Academy shall seek to influence academic institutions, federal and state regulatory agencies, fiscal intermediaries, professional organizations and the general public towards the acceptance of the professional doctorate in audiology (Au.D.) as the preferred entry-level degree for the practice of audiology.

Guiding Principles

The focus of an academic doctorate (Ph.D.) is on research culminating in the dissertation for the Ph.D., the focus of the professional doctorate in audiology (Au.D.) is on the development of clinical proficiency. The Ph.D. is defined as the *mark of highest achievement in preparation for creative scholarship and research, often in association with a career in teaching at a university or college*.⁵ The professional doctorate (Au.D.) is the *highest university award given in a particular field in recognition of completion of academic preparation for professional practice and does not require a dissertation for its completion*.⁵

The primary objective of the Au.D. program is to produce audiologists who are functionally competent in providing the wide array of diagnostic, remedial and other skills and services associated with the practice of audiology. Hence, there is major emphasis on the clinical learning experience. Although the professional doctorate in audiology (Au.D.) is not a research-oriented degree, it is imperative that student-practitioners be familiar with the scientific and research literature that undergirds audiology, have the knowledge and the skills requisite to evaluate and interpret the audiological and related research literature, and be able to synthesize and apply pertinent research knowledge to the problems of clinical practice.⁵

Ideally, Au.D. degree programs should be organized and implemented within sponsoring institutions, such as colleges and universities, that will provide for an

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AUDIOLOGY



independent school and faculty and should be constituted similar in nature to the degree programs which grant doctorates in other professions, such as dentistry, medicine, optometry, veterinary medicine, etc. Traditional graduate programs are structured to grant academic doctorates rather than professional doctorates. Consequently, Au.D. programs should be administered whenever possible independent of existing graduate school programs.⁶ They should be practitioner and patient-service driven, i.e., the basic orientation of the training programs should be to facilitate the development of the highest level of audiological skills in the student-practitioner with concomitant emphasis on delivery of superior audiological services to the patient.

Considerable responsibility falls upon the clinical and academic faculty. It must be large and diverse enough to represent to the student-practitioners the leading edge of hearing care skills and services. Didactic instruction should focus on direct application of audiological sciences to hearing care needs.⁴ The faculty and the sponsoring institution will have the ultimate responsibility to evaluate formally the student-practitioner's progress and to assess the student-practitioner's mastery of the program's content, pursuant to the awarding of the Au.D. degree.

The AAAudiology is fully aware the implementation of the professional doctorate in audiology (Au.D.) contains significant challenges and departures in audiological education, and will foster and seek cooperative effort between itself and degree granting institutions to develop programs jointly acceptable to the AAAudiology and related professional organizations.

The Clinical Training Program

The Au.D. educational process assumes development of broadly based clinical rotations based on substantive academic achievement. The preparation of the complete practitioner rests upon three essential foundations:

- Mastery of the audiological knowledge base (See Appendix)
- Extensive clinical experience and rotations
- Role modeling based on exposure to experienced, practicing clinicians

It is recommended that the student receive between 2500 and 3000 hours of clinical experience with an extensive variety of cases and preceptors. Student-practitioners should be exposed extensively to diverse and challenging clinical populations. Appropriate clinical training environments should include but not be limited to:

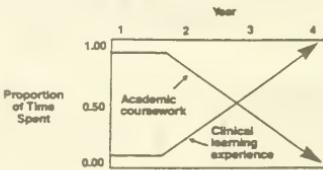
- Audiology/Medical practices
- Autonomous private practices in audiology
- Community clinics
- Hospitals

Industrial settings

- Local education agencies
- Schools for the hearing-impaired

University or college clinics

At least four separate rotations from the above list are recommended as a minimum as the student progresses through the program of study. The process of clinical experience should evolve in scope and complexity from limited clinical exposure with close supervision during the first years, to fourth year independent status. Whereas the first two years of the program are heavily weighted towards didactic classes and program are heavily weighted towards didactic classes and laboratory coursework, emphasis during the second two years shifts to clinical learning experiences.⁴ The proportion of clinical learning experiences as compared to academic instruction during the professional doctorate (Au.D.) program is depicted below.



Appendix

The intent of this section is to specify general areas of study which are considered essential to the knowledge base of the audiologist-practitioner.⁷ It is understood that the exact specification of curriculum and emphasis is the responsibility and property the domain of the educational institution that offers the Au.D. degree. As in most professional degrees, a basic science core is essential. This core can be provided by basic science faculty from other departments and schools within the degree granting institution. The following general areas of study are recommended.

Basic science areas include:

- Physics of sound, acoustics, psychoacoustics
- Research methods and statistics
- Speech science and perception
- Computer science
- Electronics, instrumentation and calibration
- Gross anatomy, neuroanatomy and neurophysiology
- Anatomy and physiology of hearing

- Diseases and pathologies of the ear and nervous system
- Related medical diagnosis and treatment
- Embryology and genetics
- Clinical pharmacology
- Epidemiology
- Radiographic techniques and imaging

General areas of professional instruction include:

1. Audiologic assessment
 - Case history/interview techniques
 - Physiologic measurements
 - Electrophysiologic measurements
 - Behavioral tests of auditory function
 - Communication measurement scales
2. Medical considerations
 - Audiologic manifestations of ear disease
 - Clinical diagnosis and evaluation of auditory pathology
 - Clinical decision analysis
3. Clinical decision process/counseling
 - Counseling strategies and techniques
 - Referral procedures and case management
 - Interprofessional relationships and responsibilities
 - Personal and interpersonal dynamics
4. Professional issues
 - Ethical/legal/quality improvement issues
 - Fiscal intermediaries/government agencies
 - Practice management/healthcare marketing
 - Forensic audiology
5. Conservation of hearing and prevention of hearing loss
 - Public and consumer education
 - Hearing conservation models
 - Identification and screening models
 - Federal/state regulations
 - Worker's compensation issues
6. Special populations
 - Pediatric audiology
 - Geriatric audiology
 - Difficult to test, including developmental disabilities
7. Audologic habilitation and rehabilitation
 - Normative developmental models
 - Auditory training
 - Visual communication, including speech reading
 - Manual communication systems and skills
 - Speech and language of the deaf and hard of hearing
 - Educational management
8. Management of amplification
 - Physical and electroacoustic characteristics of amplifying devices
 - Methods of evaluation
 - Rehabilitative procedures
 - Dispensing
 - Assistive devices
 - Implantable devices
9. Vestibular evaluation
 - Techniques and procedures
 - Rehabilitative strategies

—Denver, April 28, 1991

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ATTACHMENT I

William House, M.D.
Presidential Address
American Otological Society

American Journal of Otology

The American Journal of Otology

VOLUME 13 NUMBER 1 JANUARY 1992

1991 AMERICAN OTOLOGICAL SOCIETY MEETING PAPERS

1991 PRESIDENTIAL ADDRESS
THE TRAINING OF FUTURE OTOLOGISTS

William F. House, D.D.S., M.D.

Today there are no Renaissance men who know all there is to know about science and the humanities; there are not even any Renaissance doctors who know all there is to know about medicine and surgery or, for that matter, any doctors who know all there is to know about Otolaryngology—Head and Neck Surgery. The adage “the specialist is one who knows more and more about less and less” is true.

Today we are hearing more and more about recognizing otology as a subspecialty by designating ourselves as having “added qualifications.” I fully support this as a move in the right direction. But, and there is always a but, if we are to improve the standards of otologic practice through encouraging young doctors to seek added qualifications in otology we, the presently practicing otologists, must actively lead the way in specifying what the ideal training of an otologist should be.

There is a tendency in medical specialty training to add another year and yet another year. I am personally opposed to this because I feel it is a waste of talent and impractical in today’s cost-conscious medical environment. I feel strongly that young otologists should become board-certified otolaryngologists with added qualifications in otology within four or five years after finishing medical school. This goal can only be accomplished if we allow our residents in otolaryngology to elect to become otologists after one year of entering residency. This means the last three years of the residency would be spent as an otology resident.

I am not aware of any residency or fellowship program that covers the entire area of knowledge that I consider necessary to develop the complete otologist. I believe, however, that if we had three years, we could introduce training in these fields. These areas of knowledge should include the following:

1. Certainly during the entire three years the otology resident should be involved with increasingly complex otologic, neurologic, and skull base surgical procedures.

2. Basic neurophysiology of the ear, neurology, and neurosurgery should be included.
3. Audiology and the theory of hearing and balance measurement with sufficient hands-on involvement in hearing and balance testing to become proficient is important.
4. Actual hearing-aid selection and fitting is essential. If hearing-aid licensing is necessary in the state where the otologist is to practice, this license should be obtained during the training.
5. Working with children who have hearing impairments attributable to serous otitis, those needing hearings aids, and those who need cochlear implants, is a vital part of the otologic residency program. This is the broad field of Pediatric Otology.
6. An understanding of speech and language development and the assessment of speech and language is important if the otologist is to understand the relationship of hearing loss and how effective the child’s hearing aids or implant are in allowing the child to develop speech and language.
7. The principles of education of the hearing-impaired child should be understood and the resident should spend time observing parent-infant programs and classrooms of hearing-impaired children.
8. Finally a basic study of electronics particularly as it pertains to amplification systems should be included.

Getting all of the above expertise into a three-year residency program will not be easy. But, like all journeys of a thousand miles, we must begin with the first step. The first step is for us as otologists to recognize what is needed in the training of our future otologists and to keep the pressure on to have residency programs set up to allow a three-year otology track. During these three years the otology residency must include all of the information that the complete Renaissance otologist should know.

ATTACHMENT J

**Hearing Care / Vision Care
Parallelism in 1991**

**Table 1: Comments submitted to the
Food and Drug Administration, 1991**

American Academy of Audiology

Hearing Care/Vision Care Parallelism in 1991	
Vision Care	Hearing Care
	Physician Specialist:
Ophthalmologist	Otolaryngologist
M.D. Degree	M.D. Degree
Residency training	Residency training
Board Examination and Certification	Board Examination and Certification
Medically evaluates and medically/surgically treats diseases of the eye	Medically evaluates and medically/ surgically treats disease of the ear
May dispense vision aids	May dispense hearing aids
May employ an optometrist	May employ an audiologist
	Non-Physician Professional Specialist:
Optometrist	Audiologist
O.D. Degree	B.A.+M.A./M.S. Degree w/ approved curriculum
National Examination/State Licensure	CFY ext. training
Licensed in 50 states	National Examination/Certification/State Licensure
Professionally assesses vision for purposes of fitting corrective lenses.	Licensed in 38 states; licensure pending in others.
Refers for medical evaluation & treatment when indicated.	Professionally assesses hearing for purposes of fitting hearing aids.
Training includes medical referral indications.	Refers for medical evaluation and treatment when indicated.
Dispenses contact lenses, eyeglasses and low vision aids.	Training includes medical referral indications.
Provides visual training.	Dispenses custom in-the-ear/canal, behind-the-ear aids and assistive listening devices.
Approximately 26,000 practicing.	Provides aural rehabilitation training.
Evaluates and prescribes 60% of corrective lenses in U.S.	Approximately 8000 practicing (4% growth/year)
	Evaluates, fits and dispenses 59% of all hearing aids in U.S.
	Device Vendors:
Optician/Ophthalmic Dispenser	Hearing Aid Dealer
Optician course of study prescribed by state.	Varies with state. No formal state-approved courses of study exist.
State examination/ registration/licensure	Varies with state.
Regulated in 22 states.	Regulated in 47 states.
May only fit corrective lenses as prescribed by Optometrist or Ophthalmologist.	May evaluate, select and fit hearing aids.
May not evaluate for selection/fitting of corrective lenses.	May employ an audiologist.
May employ an optometrist.	
	Devices:
Approximately 60,000,000 lens prescriptions in 1990.	Approximately 1,600,000 aids in 1990.
Contact Lenses (15% + 10% with eyeglasses)	Custom in-the-ear/canal hearing aids (80%)
Eyeglasses (60%+10% with contact lenses)	Behind-the-ear hearing aids (20%)
Low vision aids	Assistive Listening devices
Contact lens blanks	Custom aid faceplates
	FDA:
Defers to individual states to establish conditions of sale.	Requires medical clearance or waiver for fitting of aid.
	Does not recognize audiologist as point of entry into hearing care system. Preempts state regulations.
	States:
In all 50 states of the U.S., both optometrists and ophthalmologists have the right to prescribe, fit and dispense eyeglass and contact lenses.	All states are preempted by FDA regulations.
No prior medical clearance is required.	Medical clearance or waiver is required.

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